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PRINCIPAL INVESTIGATOR: Stefania Fatone, Ph.D.

CONTRACTING ORGANIZATION: Northwestern University
Evanston, IL 60208-0001

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Stefania Fatone, Ryan Caldwell, Oluseeni Komolafe, Brian Robillard, Steven Gard, Wei Chen, Cheng Sun, Andrew Hansen, Brian Ruhe

E-Mail: s-fatone@northwestern.edu

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14. ABSTRACT

The purpose of this project is to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. The Specific Aims are to: A1. Develop a highly flexible socket with sub-ischial trim lines; A2. Develop durable liners and sealing sleeves; A3. Develop/identify an appropriate vacuum pump; A4. Evaluate system performance with military amputees; and A5. Develop education materials. During Year 3, for Aims 1 and 2, we have developed a process for automated fabrication of the socket. For Aim 3, we have created a working prototype of the hybrid mechanical-electrical pump design. For Aim 4 we have enrolled 4 of the 6 subjects and testing is underway. For Aim 5, we have continued development of education materials to facilitate dissemination of this technique.

15. SUBJECT TERMS
Transfemoral amputation, sub-ischial socket, prosthesis, vacuum-assisted suspension

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INTRODUCTION

The objective of this project is to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. We are focused on developing prosthetic socket technology that will enhance user activity by maintaining residual limb volume; improving active range of motion of the hip; improving coupling between the limb and socket; and increasing comfort during sitting, standing, walking, and running in highly active transfemoral prosthesis users. The Specific Aims of this project are to: **A1.** Develop a highly flexible socket with sub-ischial trim lines; **A2.** Develop liners and sealing sleeves that are durable for highly active users; **A3.** Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis; **A4.** Evaluate system performance with transfemoral prosthesis users; and **A5.** Develop education material for sub-ischial socket design. Human performance will be evaluated at the Center for the Intrepid in the third year of funding. For Aims 1 and 2, we are using engineering analysis and an advanced manufacturing approach to improve the socket and liner. For Aim 3, we have identified options for vacuum pumps, characterized commercially available vacuum pumps, and designed a hybrid mechanical/electrical pump for persons with transfemoral amputation. Supplemental funding allows us to construct a working prototype of the hybrid pump for further testing. For Aim 4, highly active persons with unilateral transfemoral amputation are being recruited to evaluate system performance and provide important feedback on the design. For Aim 5 we are developing education materials based on quantification of the socket rectification and fabrication process. This project provides an improved prosthetic socket technology for the clinical care of highly active military service persons with transfemoral amputation. Increased comfort, hip range of motion and coupling between the residual limb and prosthesis will result in increased functional performance of individuals with combat-related transfemoral amputations. Furthermore, improvements in socket comfort and coupling would benefit all persons with transfemoral amputation, regardless of their activity level.

BODY: PROJECT PROGRESS

What follows is a description of the work conducted during Year 3 of our project. Our progress is presented with respect to the Aims and Tasks described in our grant application, with progress on each task indicated on the corresponding section of the approved statement of work (Gantt chart). Overall, we have made good progress on the tasks in Aims 1 and 2, completed most of the tasks in the original Aim 3 and are working on the supplemental tasks, begun work on Aim 4, and made progress on the tasks in Aim 5.

We plan to continue work on the project during a one year extension without funds. This extension was requested in part because in February 2013 Otto Bock announced discontinuation of sales of Polytol, which is the material that formed the flexible component of our socket. This has necessitated a search for a replacement material that has set us back with regards to our ability to complete the project. Our search to date has identified at least one promising material, but more time is needed to establish suitability for use in our socket and with both the manual and automated fabrication techniques. Once a new material is identified we will need to repeat some portions of Task 3 to ensure it can be fabricated using our automated approach,

Task 4 to establish performance characteristics, Task 5 to solicit feedback from subjects using sockets made from the new material, and Task to 12 incorporate new material information in the education materials.

Task 1 Initial preparatory activities

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Task 1 Initial preparatory activities.												
1a Convene initial project meeting.												
1b Prepare and submit IRB application.												

1a Convene initial project meeting: *This task is complete.*

1b Prepare and submit IRB application: *This task is complete.*

Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users

We have begun the search for a new flexible lamination material. Initially Orthomerica was contacted to see if their foam padding (an EVA foam compressed under vacuum) would be suitable to create the inner and outer flexible components of the socket. This material was explored as it is used to make a spinal orthosis that has a frame embedded between two layers of the foam – a technique similar to our socket fabrication. Unfortunately, we were unable to get the padding material in the cone shape required to fabricate sockets.

A small sample lamination was made with Polytek urethane rubber (a material that can also be used with the advanced manufacturing approach described in Task 3) (Figure 1). The inner surface of the lamination appeared to be fine but the outer surface was not smooth as the PVA bag stuck to the material. Other than this issue, the material looked promising, so a full-scale socket was made from Polytek. We tried to hand fabricate a two stage socket where the frame was made of a single blister formed sheet of 1/2" polypropylene over 7 ply of socks to accommodate the thickness of the inner layer of Polytek (this is in place of the 4 stage process required for our Polytol sockets). The frame was finished and then the inner and outer fiber-reinforcement material put in place for a single lamination. The Polytek saturated most of the inner and outer layers, which was good for the first attempt. However, the PVA bag continued to stick to the outer lamination, which would clinically be an issue. Three different mini versions of the Polytek socket were made in an attempt to resolve these issues with the fabrication process. Two sockets were made using a PVA bag with release agents but the PVA bag still stuck to the rubber. For the third attempt we used a PVC bag, which was successful in stopping the bag from sticking to the rubber. Additionally, the finish on the inside of the socket was nice and

smooth. While Polytek worked reasonably well with the PVC bag, the working time of 5-7 minutes was inadequate to properly wet out all the fibers, hence we continue to explore material options.

A full size socket was made from the polyurethane two part resin, Fiberglast (another material that can also be used with the advanced manufacturing approach described in Task 3) (Figure 1). Fiberglast allows for a 10-14 minute working time, which is manageable for our lamination requirements. The Shore 60-D resin durometer used initially resulted in socket flexibility that was less than optimal (this durometer is more plastic and less elastic; equivalent to a construction hard hat). The PVC bag did a good job of providing a smooth surface to the lamination and a 2-stage process was implemented with few issues.

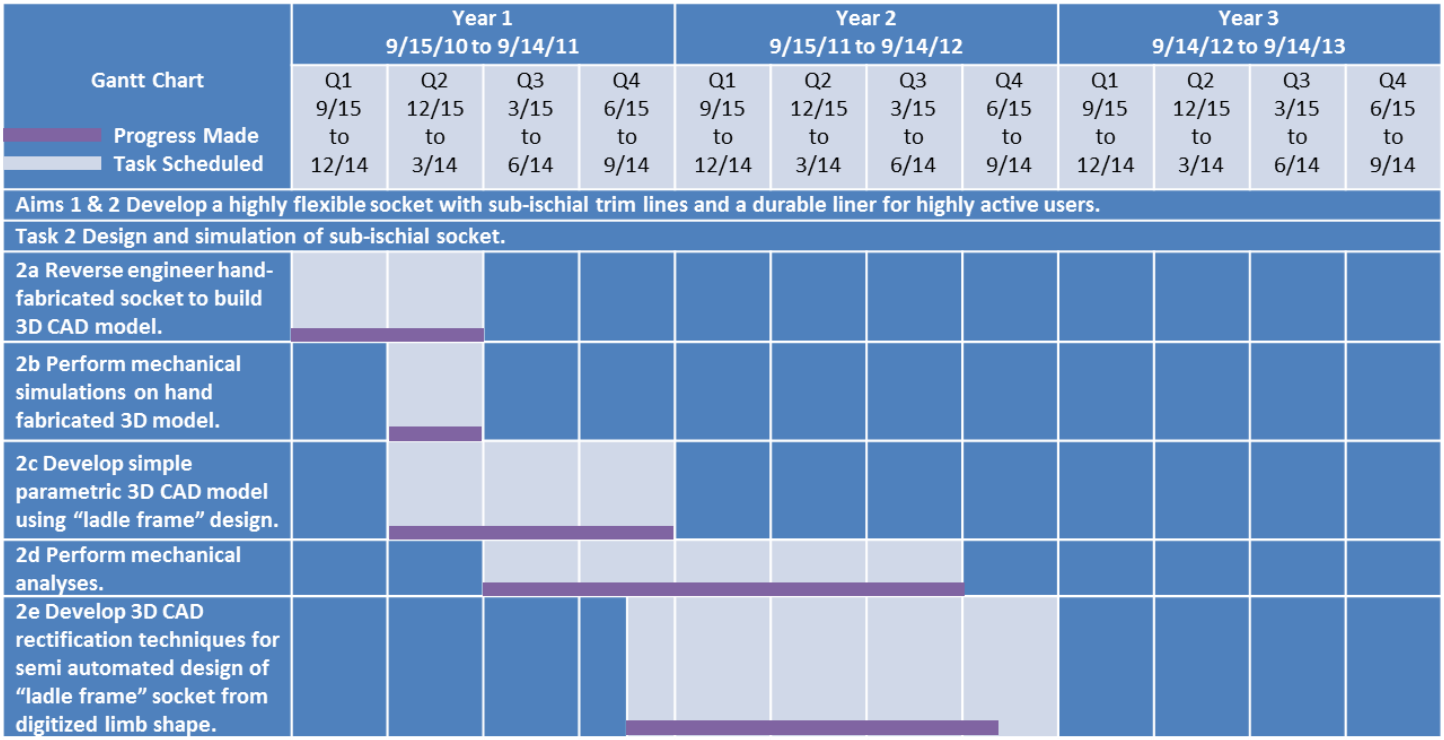
A second small scale Fiberglast socket of Shore 60-A durometer was fabricated with a polypropylene frame (Figure 1). While this durometer appeared to result in a socket closer to the material properties of Polytol, it was still slightly more plastic than elastic. Hence, we tried a full-scale socket with Shore 60-A durometer Fiberglast using 4 nylons instead of 4 spectra and replaced one layer of Dacron with lycra. The PVC bag was removed from the inner and outer surface easily and in some areas came off by itself. Unfortunately, when we tried this socket on one of our test subjects, it was too flexible for the subject to use successfully. The subject felt too much give in the proximal brim when he donned the socket: a sign that the socket would not be good for walking. Another full-scale, less flexible Fiberglast socket has been fabricated with the same lay-up as the original Polytol socket (consisting of spectra and spectracarb aralon layers with a Dacron layer as the inner and outer-most layers). However, the carbon and kevlar frame materials were replaced by polypropylene that was blister formed and trimmed to form the “H” frame. Upon visual inspection, the layup and hardened material appeared to be similar in feel to Polytol. Another feature of Fiberglast that we think might be useful is that the resin can be laminated with lycra or stretch nylon as the outer layer, potentially providing an even more durable layer than Dacron. We think it will be less likely to become fuzzy without the Dacron.

Figure 1 Different socket materials explored as replacements for Polytol.

We will continue searching for and testing alternative flexible lamination materials during the extension without funding period. We are also exploring components (e.g. socket attachment plates) and fabrication methods to ensure a two-stage process can be implemented, making socket fabrication more clinically viable. These elements may further improve the strength/failure limits of the socket as the socket attachment plate can be

completely embedded in the frame. The socket attachment plate was the point of failure in the testing we conducted on our Polytol socket (see Task 4b).

Task 2 Design and simulation of sub-ischial socket



Task 2a Reverse engineer hand-fabricated socket to build 3D CAD model and FE model: *This task is complete.*

Task 2b Perform mechanical simulations on hand-fabricated 3D model: *This task is complete.*

Task 2c Develop a simple, parametric 3D CAD model using "ladle-frame" design: *This task is complete.*

Task 2d Perform mechanical analyses: *This task is complete.* The models used for simulation were based on direct scans of the flexible lamination and rigid frame components of physical sockets taken as part of Task 2a. Three models with different rigid frame designs (completely rigid, ladle frame, H-frame) were analyzed computationally to quantify the effect of rigid frame type and thickness on the mechanical functioning of the socket. The output of the simulation was the prosthetic socket deflection computed as an average of the deformation along the three principle axes (X,Y,Z). A similar analysis was performed with the stress distribution calculated as the simulation output. These results were presented at the 2013 World Congress of the International Society for Prosthetics and Orthotics and the 2013 Annual Meeting of the American Academy of Orthotists and Prosthetists. The protocol and results are summarized below.

a. A simple template was developed to partition the different socket geometries into discrete regions, along which the simulation results are compared (Figure 2).
b. Results of the average displacement of the socket analysis regions for the three different frame designs (Figure 3).

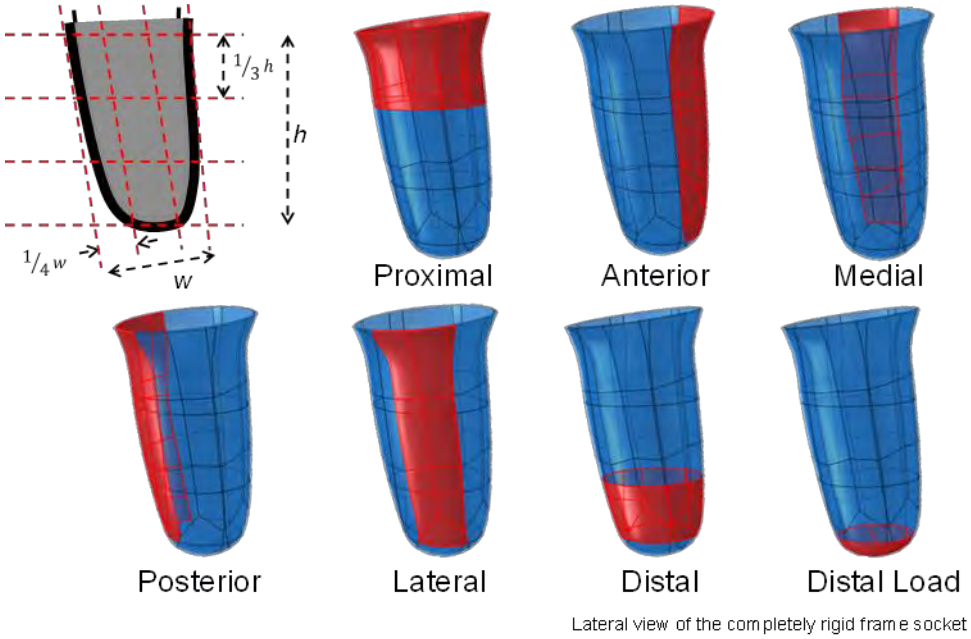


Figure 2 Analysis regions of the H-frame.

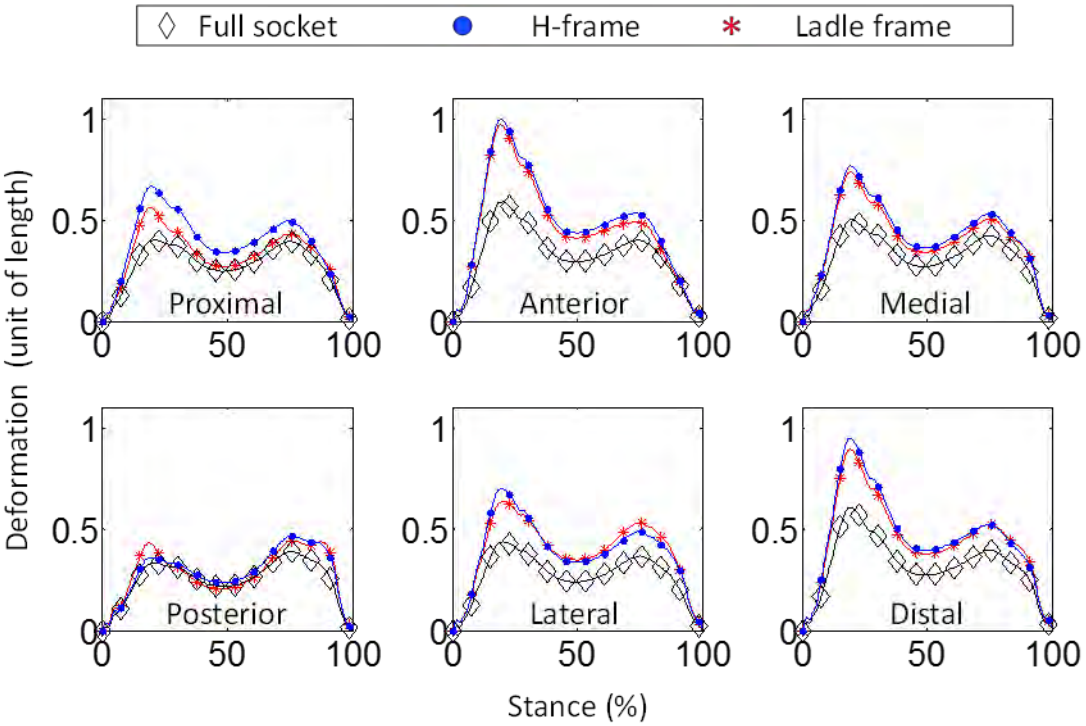


Figure 3 Quantitative analysis of average deformation for different frame designs assessed along the analysis regions shown in Figure 2.

A manuscript describing our FE analysis has been prepared for publication. It is currently undergoing internal review and will be submitted shortly.

Task 2e Develop 3D CAD rectification techniques for semi-automated design of "ladle-frame" socket from digitized limb shape: *This task is in progress.* Summarized below with Task 11e.

Task 3 Advanced manufacturing of sub-ischial sockets

During Year 3, Northwestern University biomedical engineering graduate student, Brian Robillard, was recruited to work on Task 3 as part of his Master's thesis which will be submitted in June 2014.

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 3 Advanced manufacturing of sub-ischial sockets.												
3a Establish criteria and techniques for multi-shot cavity molds.												
3b Develop degassing techniques for liquid resin molding.												
3c Develop proximal brim vacuum seal.												
3d Develop mechanical interlocking molding techniques.												

Task 3a Establish criteria and techniques for multi-shot cavity molds: *This task is complete.* The current workflow for generating the digital residual limb geometry input files for advanced manufacturing of sockets is depicted in Figure 4.

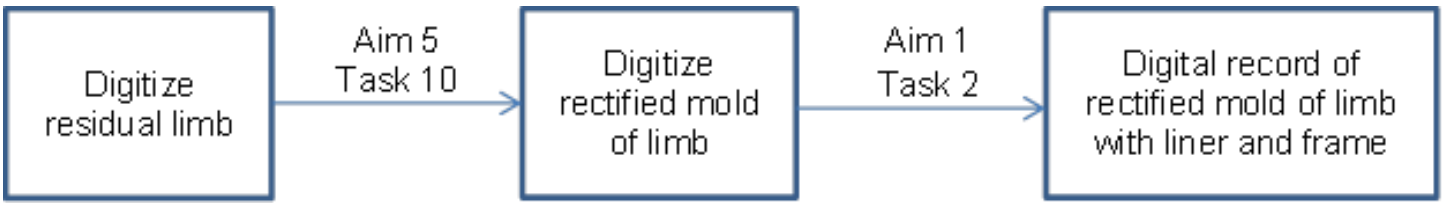


Figure 4 Current work flow for input to advanced fabrication process.

Initially, two general approaches for a two-shot molding process were explored: horizontal and vertical cavity molds (Table 1). While both approaches evinced similar accuracies, time savings were evident with the horizontal approach due to a faster demolding process, however the vertical approach had minimal leaking. The minimal leaking was what ultimately led us to commit to a vertical approach. Additional descriptions of these two approaches may be found in Appendix A.

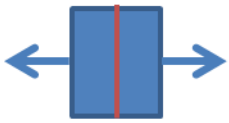
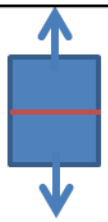
Approach	Pieces requiring fabrication	Number of pours required
Horizontal 	5	2
Vertical 	3	2

Table 1 Cavity mold options for two-shot molding.

With additional trials, direct manufacture of the frame and injecting the resin into the frame-layup simplified the process to a single-shot mold providing additional time and cost savings. Additional description of this approach may be found in Appendix B.

The final fabrication technique developed using an iterative design process uses a handheld scanner to scan a positive mold of the residual limb, SolidWorks to process the digital model, a Stratasys FDM 400mc to build the mold components, and a single-shot molding technique to fabricate the socket using additive manufacturing. A poster describing this process was presented at the Northwestern University Research Day (Appendix A) and another has been accepted for presentation at the Biomedical Engineering Society (BMES) Annual Meeting (Appendix B).

Task 3b Develop degassing techniques for liquid resin molding: *This task is complete.* With the process described in Task 3a, we encountered two gas related issues: air bubbles (introduced during the filling process) and air spaces (areas of low/failed resin flow). The use of vacuum during the pour process was found to reduce air bubbles while the introduction of "over-flow" ports maximized the amount of resin introduced into the cavity molds and reduced air spaces. Appendix C provides a description of the development process.

Task 3c Develop proximal brim vacuum seal: *This task is complete.*

Task 3d Develop mechanical interlock molding techniques: *This task is complete.* We are using holes in the printed frame to facilitate resin flow to both sides of the frame and create a mechanical interlock between the two flexible laminations. Appendix C provides a description of the development process.

The single-shot molding process designed to fabricate a three-layer prosthetic socket has demonstrated feasibility, but the socket's clinical applicability remains to be determined. In order to assess the clinical utility of

our advanced manufacturing approach to socket fabrication, we plan to compare failure loads and modes to two other sockets: first to a manually fabricated socket to assess how the two approaches compare overall and second to a manually fabricated socket fabricated using the same materials as the advanced manufacturing approach. We will compare the sockets using the same failure, tensile, flexural, and peel tests used in Task 4.

One advantage of advanced manufacturing is the ability to create a prosthetic socket with precise dimension parameters. Hence, we plan to employ our finite element model to explore the effect of prosthetic socket frame thickness variations on stress distribution in the socket. We will compare different prosthetist-recommended frame thickness profiles at the transition regions between the rigid and flexible portions of the socket. Gradated regions will be defined by their area and percent of gradation.

Task 4 Mechanical bench testing of sockets and liners

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 4 Mechanical bench testing of sockets and liners.												
4a Perform peel tests of bond strength.												
4b Perform socket strength and deflection tests.												
4c Perform indentor tests of elastomers.												
4d Perform sitting durability tests.												
4e Perform cyclic evacuation tests.												

Task 4a Perform peel tests of bond strength: *This task is complete.*

Task 4b Perform socket strength and deflection tests: *This task is complete.* Three sockets were fabricated and were sent to Ohio WillowWood for strength testing according to their published protocol (Gerschutz et al., 2012). The testing was based on a modified ISO 10328 Configuration II A125 test set-up. All three sockets failed at the distal adapter location similar to other socket designs fabricated in the general prosthetic community and tested using this protocol (Figure 5). The full results are described in Appendix D.

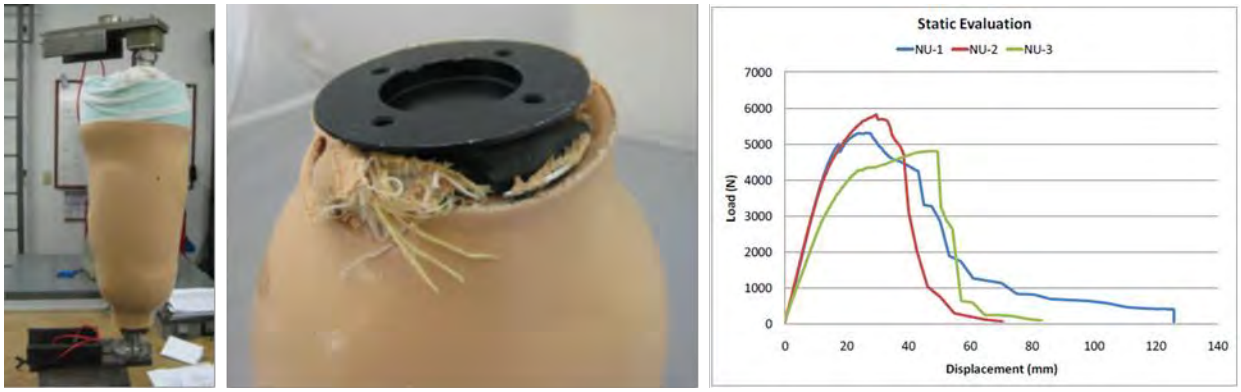


Figure 5 Excerpt from Appendix D showing (from left to right) test set up, failure mode, and force deflection curves.

Task 4c Perform indentor tests of elastomers: *This task is complete.*

Task 4d Perform sitting durability tests: *This task was revised and is complete.* Summarized below with Task 4e.

Task 4e Perform cyclic evacuation tests: *This task was revised and is complete.* Initially, we believed the conditions mainly responsible for liner failure were repeated pinching and shear of the liner between the hard socket and a sitting socket (Task 4d) as well as stressing of the liner that occurs on the socket brim when vacuum is applied (Task 4e). However, further interactions with users of prosthetic liners suggested the primary mode of failure to be a knife edge action of the brim of the rigid socket through the side of the liner. To reflect this new information, we revised the testing approach for this task. Here, the liner was stretched over two different socket edge types. The first, a flexible edge is representative of the prosthetic socket developed in this study. A flexible lamination is fabricated over the rigid material of the structural frame. The second, a rigid edge is typical of non-flexible prosthetic sockets typically used clinically. The test results (Figure 6) show the liner failure loads with the knife edge action is about 23% higher for a flexible frame compared to a rigid frame. The higher variability of the failure loads of the flexible edge confirms the ductile liner failure observed during the testing.

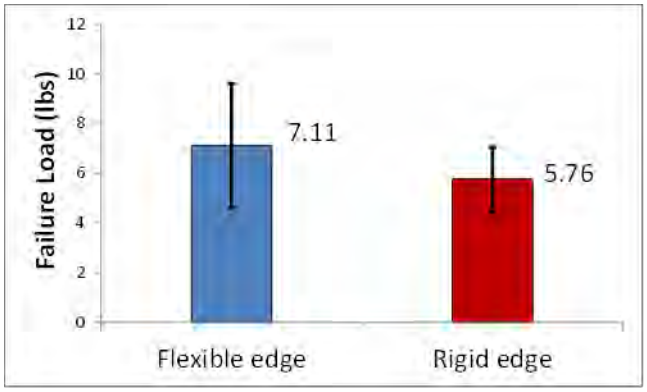


Figure 6 Mean and standard deviation of the load at failure of liners when stretched over flexible and rigid socket brims.

Task 5 Solicit feedback from human subjects

Gantt Chart	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13				Extension without Funds 9/15/13 to 9/14/14			
Progress Made / Task Scheduled	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.																
Task 5 Solicit Feedback from human subjects.																
5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects.																

Task 5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects: *This task is in progress.* Our two test subjects continue to provide feedback regarding different versions of the socket. While liner durability and socket comfort have proven acceptable during every day, high level activities, we continue to search for improvements. Subjects have worn the Polytol subischial socket with different commercially available liners (e.g. Össur Comfort Cushion liner, Össur Synergy liner, Medi Relax liner) and provided feedback. While the Medi liner works well, an alternative is needed for amputees who have a residual limb shape that is not conducive to the umbrella shape in the liner. As a result of conversations with Össur, they have provided us with prototypes of a new liner that combines the properties of two commercially available liners: the dual durometer silicone of the Össur Synergy and the textile covering of the Össur Sport liner. These have been combined to create a single liner with properties we think valuable for successful use of our subischial socket. Regardless of liner type, durability has been good when used in conjunction with the flexible lamination but remains an issue when checking liner fit with rigid test sockets. For example, one of our test subjects has used the same liner for all three years of the project. The same subject reported less problems with sweating during running when his liner was perforated (this idea was suggested by work reported at the recent ISPO World Congress: McCarthy et al. 2013). We plan to continue working with these two subjects during the extension without funding period to get feedback on new socket materials and the advanced manufactured sockets.

Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis

Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users

Gantt Chart	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13				Extension without Funds 9/15/13 to 9/14/14			
Progress Made Task Scheduled	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.																
Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users.																
6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test).																
6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users.																
6c Compare results of 6a and 6b.																

Task 6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test): *This task is complete.*

Task 6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *The originally planned portion of this task is complete and additional work is in progress.* We have collected and analyzed data from 16 subjects with unilateral transfemoral amputation. During Year 3 we continued to experience delays associated with subject recruitment. As noted in our Year 2 Annual Report, our clinical collaborator Ryan Caldwell had to reconstitute his patient referral base after a change in his clinical employment. While progress was made in that regard, the loss of Polytol substantially affected Ryan’s clinical practice and, hence, the availability of subjects for Tasks 6 and 11. We will work during the extension without funding period to recruit the additional subjects needed to complete this task.

Task 6c Compare results of 6a and 6b: *This task is complete for initial data.*

Task 7 Characterization of mechanical and electrical pumps

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 7 Characterization of mechanical and electrical pumps.												
7a Survey and collect all mechanical and electric pumps for use in lower limb prostheses.												
7b Characterize pumps based on cycles and time to pull specific vacuum levels.												
7c Publish a journal article on the characterization of the mechanical pumps.												

Task 7a Survey and collect all mechanical and electric pumps for use in lower limb prostheses: *This task is complete*.

Task 7b Characterize pumps based on cycles and time to pull specific vacuum levels: *This task is complete.*

Task 7c Publish a journal article on the characterization of the mechanical pumps: *This task is complete.* A manuscript was accepted for publication in the Journal of Rehabilitation Research and Development (Appendix E).

Task 8 Finalize vacuum pump design

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 8 Finalize vacuum pump design.												

This task is complete.

Aim 3 Supplemental Tasks

Supplemental funding was received in December 2012 for an additional 12 months of work running concurrent with Year 3 of the project to prototype and test the hybrid vacuum pumps ability to create suitable vacuum for suspension of the prosthesis in highly active persons with transfemoral amputation.

Supplemental Task 1 Build three hybrid vacuum pumps.

Gantt Chart Progress Made Task Scheduled	1/01/13 to 12/31/13			
	Q1 1/01 to 3/31	Q2 4/01 to 6/30	Q3 7/01 to 9/30	Q4 10/01 to 12/31
Extended Aim 3: Prototype and test hybrid vacuum pumps to create suitable vacuum for suspension of the prosthesis.				
Task 1: Build three hybrid vacuum pumps.				
1a Create detailed 3D CAD drawings for all constituent parts and molds.				
1b Prototype and machine all constituent pump parts and bladder molds.				
1c Injection mold bladders.				
1d Assemble electrical pumps.				
1e Assemble prototype hybrid pumps.				

Supplemental Task 1a Create detailed 3D CAD drawings for all constituent parts and molds**:** *This task is complete.* Detailed 3D CAD drawings were created for each of the four proposed hybrid pump designs and a mold for the bladder, which is common to all designs (Figure 7). Additionally, CAD drawings of the LimbLogic pump electronics were provided to us by Ohio WillowWood. This allowed us to determine if the compartment space designed as part of the hybrid pumps is sufficient to house the components required by an electric pump system.

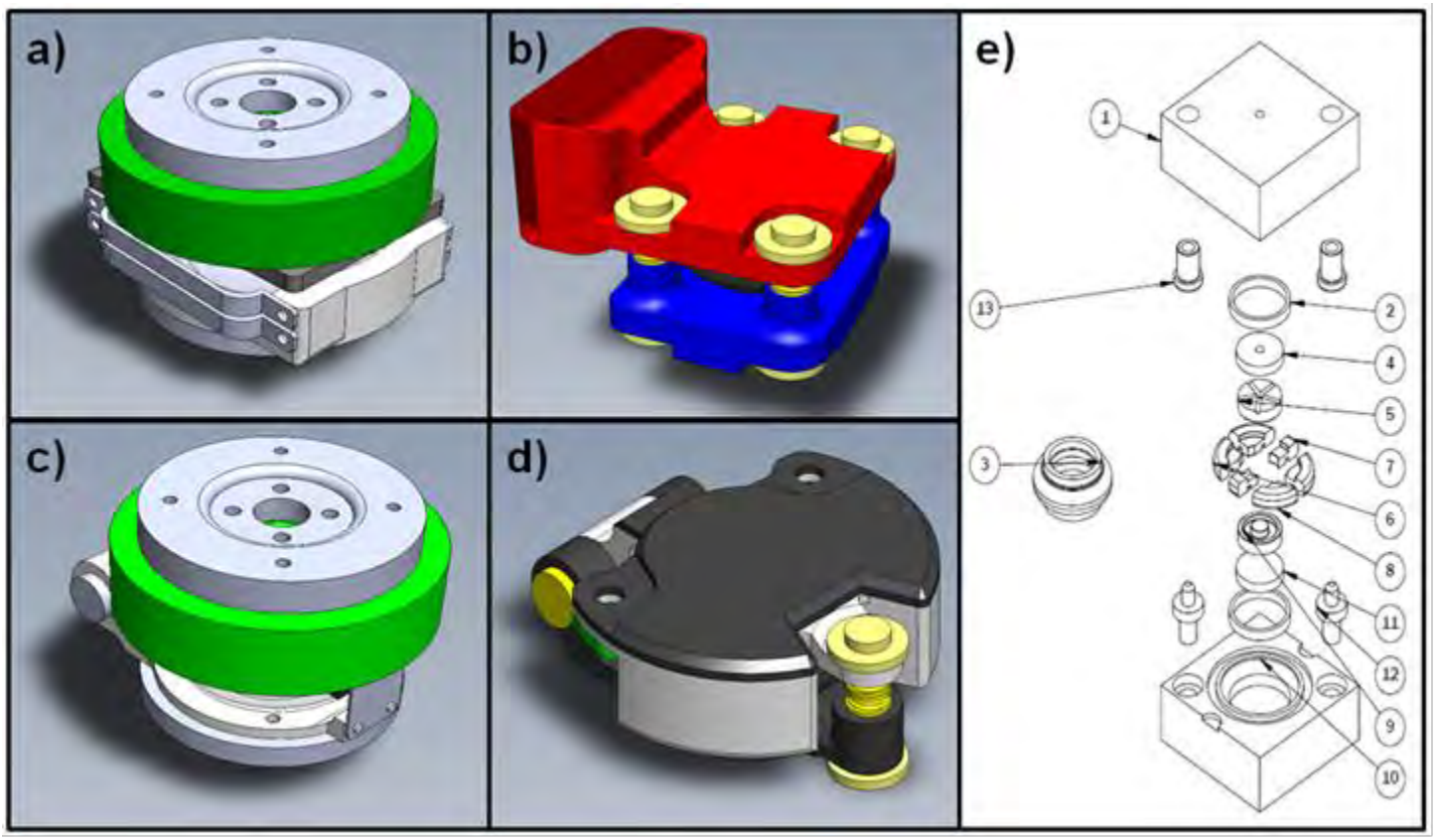


Figure 7 CAD drawings for each hybrid pump design and the bladder mold.

Supplemental Task 1b Prototype and machine all constituent pump parts and molds: *This task is complete.* Summarized below with Supplemental Task 1c.

Supplemental Task 1c Injection mold bladders: *This task is complete.* Making the bladder required access to injection molding services and as such we worked initially with Weiler Rubber Technologies LLC to manufacture the first prototype bladder. We used our Stratasys FDM system to rapid prototype one of the four designs, the four post design, to assess function of the bladder. Through a series of experiments, we determined that the bladder was unable to generate sufficient vacuum due to leakage and a lack of rebound that did not allow the pump to continue pulling air after several cycles. This rebound issue was most likely the result of too low a stiffness of the bladder material, such that it did not return to its neutral position following compression. Discussion with Weiler led to the proposed bladder design changes shown in Figure 8. The redesign was intended to address leakage by securing the proximal and distal bladder walls within a 'sandwich' plate; an improvement over the original method of securing the bladder to standard pipe fittings.

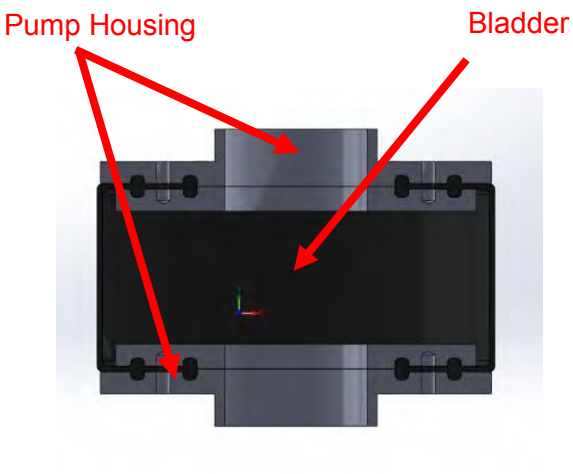


Figure 8 Proposed bladder redesign that addresses the issue of leakage by sealing the proximal and distal ends of the bladder within the walls of the pump housing.

Unfortunately, prior to fabrication of the redesigned bladder, Weiler withdrew from working on this project due to other commitments. Attempts to identify another injection molding service to work with us were unsuccessful. Hence, an alternative approach to addressing bladder design issues had to be sought. In order to demonstrate that the hybrid pump was feasible (i.e., could demonstrate concurrent function between the mechanical and electrical pumps) we decided to modify the CAD models of the pump designs such that the Otto Bock Harmony P3 bladder (referred to as the 4X147 Functional Ring by Otto Bock) could be retrofitted into the assembly for bench testing. We modified three of the proposed hybrid pump designs (hinge, four-post, and four-bar) for retrofitting with the P3 bladder, which was also modeled. The primary design modification was inclusion of a ring indentation in the housing for intimate fitting of the P3 ring and the overall build height was increased to accommodate the height of the ring. With this approach, it was unnecessary to build the fourth

iteration of the hinge design with the external spring as the P3 bladder demonstrated sufficient rebound in previous mechanical testing.

Upon preliminary analysis of each design's mechanical function with the P3 ring, issues were encountered with the hinge and four-bar designs: given the height of the P3 ring it was not possible to derive suitable linear displacement from angular displacement. The angular motion of these two designs places the P3 ring under asymmetric loads and, furthermore, the moments produced when under load act in such a way that the housing pulls itself apart. Consequently, we tested only the four-post design with integration of both the P3 ring and LimbLogic system.

Supplemental Task 1d Assemble electrical pumps: *This task is complete.* Summarized below with Supplemental Task 1e.

Supplemental Task 1e Assemble prototype hybrid pumps: *This task is complete.* Preliminary evaluation of the hybrid system involved setting up the housing in a drill press for creating linear compression and pulling 17 inHg using only the P3 ring, then creating an artificial leak in vacuum, and allowing the LimbLogic electrical system to activate in order to return vacuum to 17 inHg. Using the four-post design, the hybrid system functioned well with the mechanical and electrical components operating in tandem. For additional testing, further modifications were made to the housing of the four-post design in order to attach male/female pyramid adaptors to the distal and proximal surfaces. This required aligning the center of the (proximal and distal) pyramid attachments with the central axis of the P3 ring to ensure symmetric loading of the ring under uniaxial compression. These changes required that the posterior carriage be extended to house the LimbLogic electrical components. A hose protruded through this carriage on the distal side that attached to the volume for which vacuum was to be created. Holes were tapped on the top and bottom plate to attach the pyramid adapters and the bolts screwed into these holes were secured with an epoxy resin. An image of the final hybrid pump prototype is displayed in Figure 9.

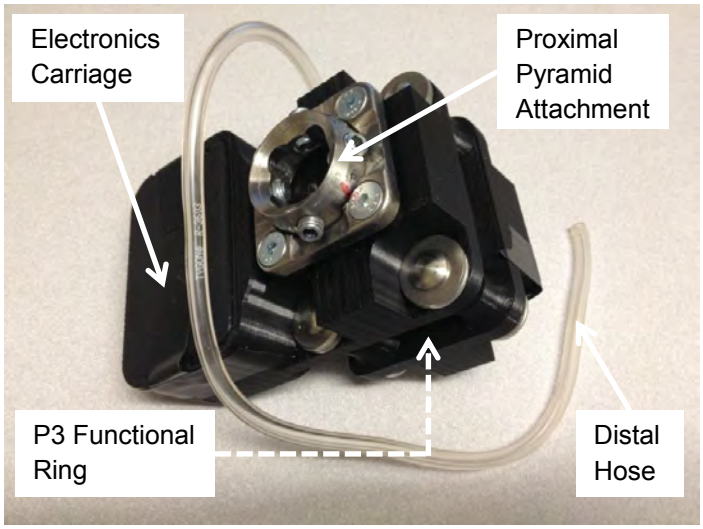


Figure 1. Hybrid Pump Prototype

Figure 9 Assembled hybrid pump (four-post design).

Supplemental Task 2 Performance testing of three hybrid vacuum pumps.

This task was revised based on the results of Supplemental Task 1 such that we only tested one pump design (the four-post design with integration of both the P3 ring and LimbLogic system).

Gantt Chart Progress Made Task Scheduled	1/01/13 to 12/31/13			
	Q1 1/01 to 3/31	Q2 4/01 to 6/30	Q3 7/01 to 9/30	Q4 10/01 to 12/31
Extended Aim 3: Prototype and test hybrid vacuum pumps to create suitable vacuum for suspension of the prosthesis.				
Task 2: Performance testing of three hybrid vacuum pumps.				
2a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test).				
2b Evaluate time needed to evacuate sockets of transfemoral prosthesis users.				
2c Compare results of 2a and 2b to previous results from 6a and 6b.				

Supplemental Task 2a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test): *This task is behind schedule.* The four-post pump design underwent mechanical characterization using the Instron materials testing machine (Figure 10, left). This characterization involved cyclical compression of the pump through a displacement of 7 mm (about 1 mm before bottoming out occurred) over 300 cycles and with a frequency equivalent to average walking cadence (100 steps/min). Canister 'C' was used as the test volume (6.46 in^3) for this assessment. The maximum axial force and vacuum pressure achieved during this characterization was 140 lbs and 13.4 inHg, respectively (Figure 10, right).

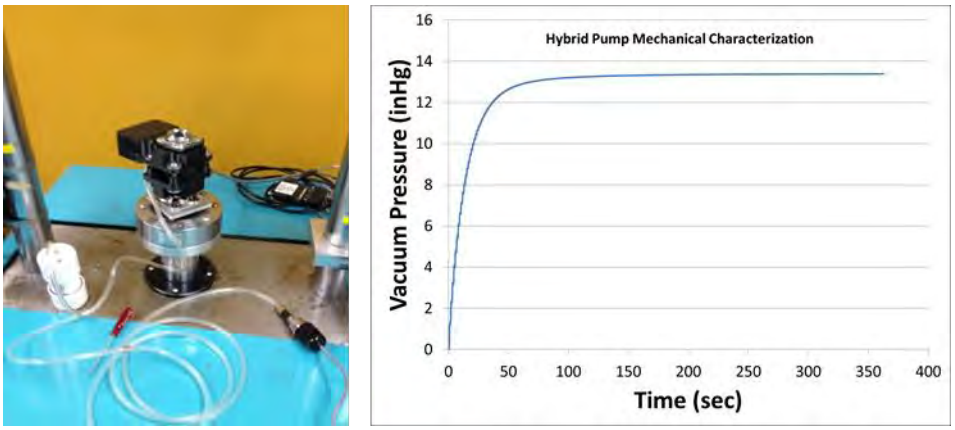


Figure 10 Mechanical test set up (left) and results for 6.46 in^3 canister (right).

Supplemental Task 2b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *This task is behind schedule.* The pump underwent a form of preliminary *in-vivo* characterization, in which it was attached between the distal end of walking boots and prosthetic feet (Figure 11). These simulators were used to subject the pump to the type and magnitude of loads experienced when installed distal to a prosthetic socket. The pump sustained the loads applied during this *in-vivo* testing without failure or damage, but

displayed asymmetric compression during walking (i.e., sequential posterior and anterior compression corresponding to heel toe gait). There is concern that this asymmetric compression pattern may be a source of discomfort when used in operation with a transfemoral prosthesis. Vacuum level was also compromised by the asymmetric compression: when the pump was compressed symmetrically it was able to pull a higher level of vacuum (~12 inHg) than when it was compressed asymmetrically (~6 inHg). Once we have successfully addressed this issue, we will work during the extension without funding period to recruit amputee subjects to test hybrid pump function.

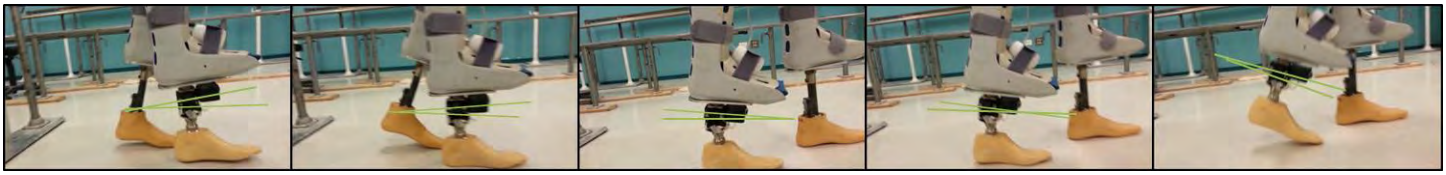


Figure 11 Walking on the four-post hybrid vacuum pump using walking boots and prosthetic feet. Green lines indicate the asymmetric loading/compression that the pump experiences during stance phase.

Supplemental Task 2c Compare results of Supplemental Tasks 2a and 2b to previous results from Tasks 6a and 6b: *This task is behind schedule.*

Supplemental Task 3 Finalize vacuum pump design.

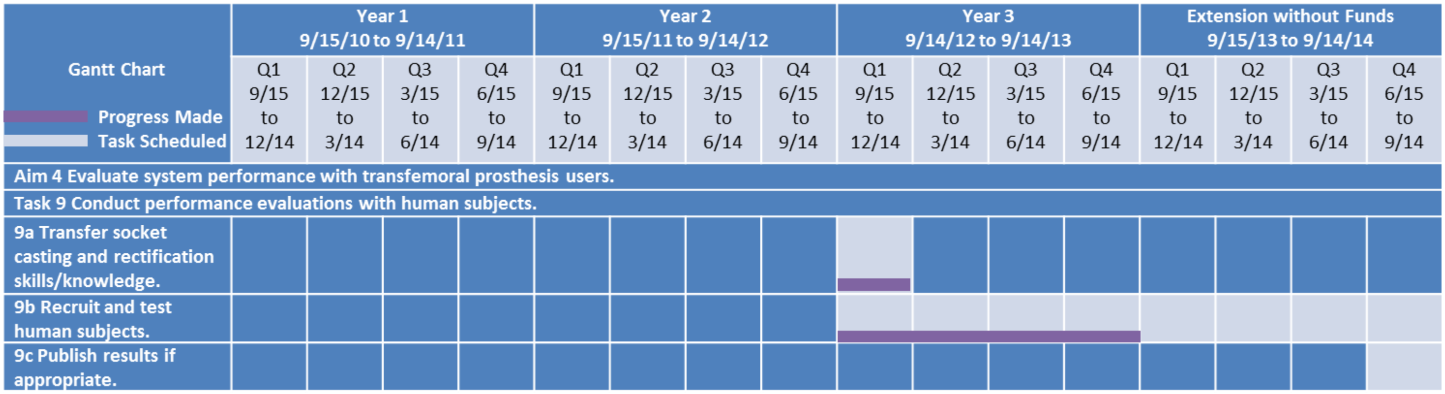
Gantt Chart Progress Made Task Scheduled	1/01/13 to 12/31/13			
	Q1 1/01 to 3/31	Q2 4/01 to 6/30	Q3 7/01 to 9/30	Q4 10/01 to 12/31
Extended Aim 3: Prototype and test hybrid vacuum pumps to create suitable vacuum for suspension of the prosthesis.				
Task 3: Finalize vacuum pump design.				
3a Iterate/refine final pump design based on performance testing.				
3b Prepare and submit presentations/publication on hybrid pump design and performance results				

Supplemental Task 3a Iterate/refine final pump design based on performance testing: *This task is behind schedule.* Design iterations are ongoing to address the issue of asymmetric compression identified in Supplemental Task 2b and reduce the coronal plane dimensions of the hybrid pump housing.

Supplemental Task 3b Prepare and submit presentations/publication on hybrid pump design and performance results: *This task is not scheduled to start yet.*

Aim 4 Evaluate system performance with transfemoral prosthesis users

Task 9 Conduct performance evaluation with human subjects



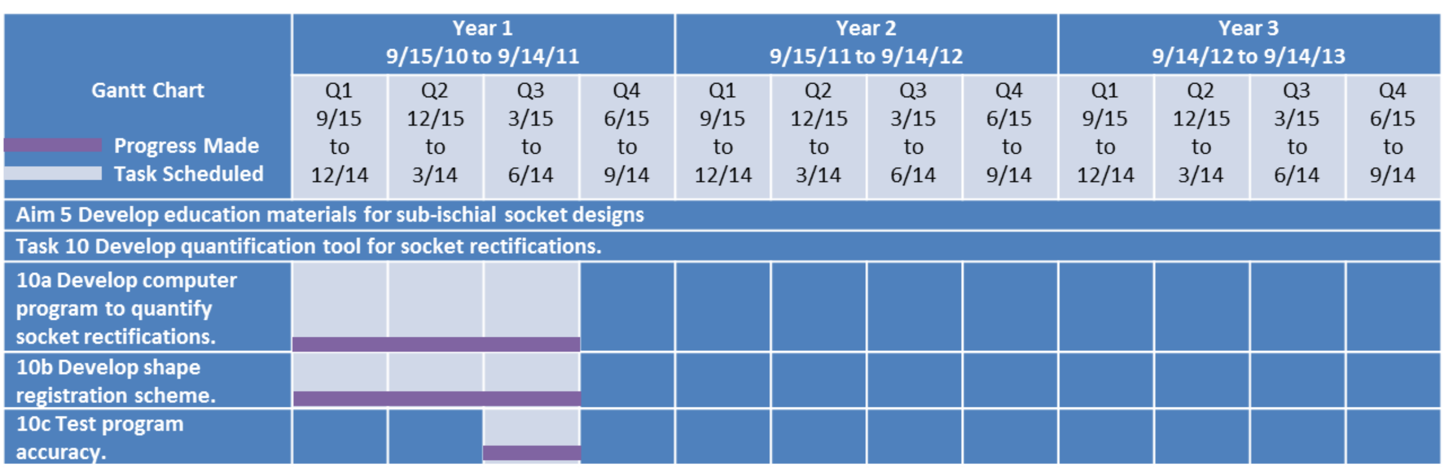
Task 9a Transfer socket casting and rectification skills/knowledge: *This task is complete.* Summarized below with Task 9b.

Task 9b Recruit and test human subjects: *This task is in progress.* Two visits to the Center for the Intrepid/Brooke Army Medical Center (CFI/BAMC) have occurred to date (October 2012 and August 2013) to cast and fit the first four subjects and in the process transition the socket fabrication and fitting technique to BAMC prosthetists. A fifth subject has been identified but not yet enrolled. Data collection is underway. We are encouraged that of the two subjects that have completed the protocol, both have converted to using our socket full time as their regular socket and are reluctant to return to their previous socket design. Recruitment of subjects at the CFI/BAMC has been slower than expected due to unanticipated complications scheduling subjects over the duration of the study protocol.

Task 9c Publish results if appropriate: *Delayed until end of extension without funding.*

Aim 5 Develop education materials for sub-ischial socket design

Task 10 Develop a quantification tool for socket rectifications

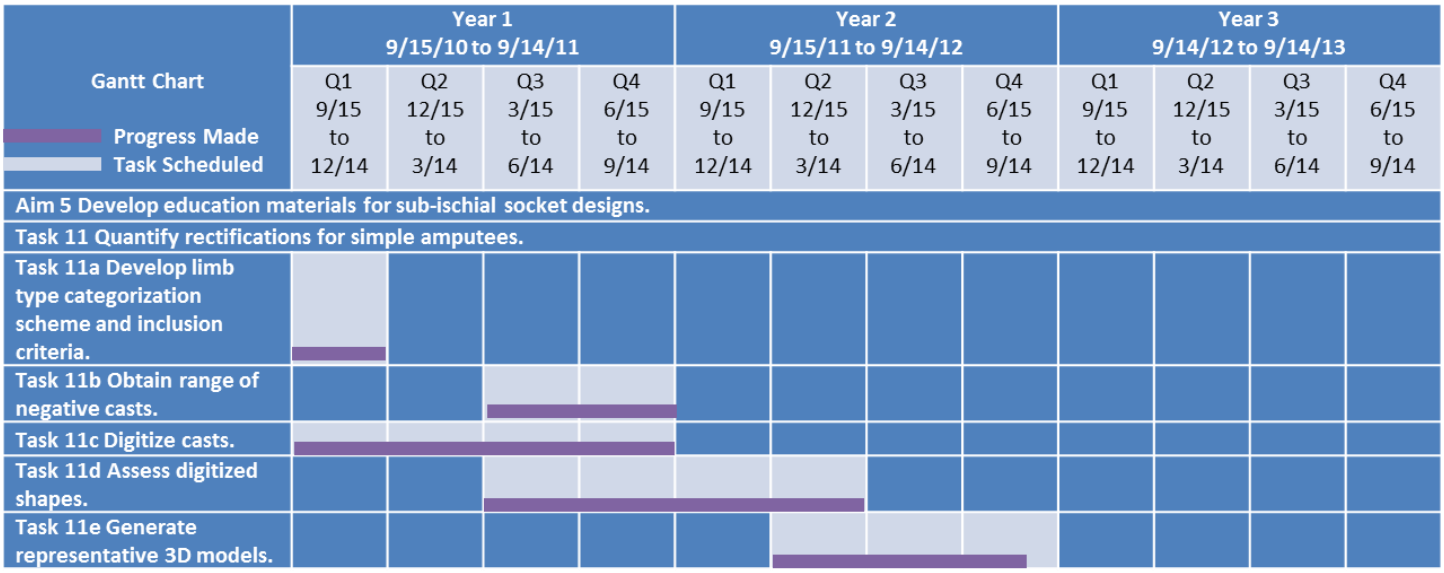


Task 10a Develop computer program to quantify socket rectifications: *This task is complete.*

Task 10b Develop shape registration scheme: *This task is complete.*

Task 10c Test program accuracy: *This task is complete.*

Task 11 Quantify rectifications for multiple amputees



Task 11a Develop limb type categorization scheme and inclusion criteria: *This task is complete.*

Task 11b Obtain range of negative casts: *The originally planned portion of this task is complete and additional work is in progress.* To date we have collected 30 pairs of casts. We are working to collect additional casts.

Task 11c Digitize casts: *The originally planned portion of this task is complete and additional work is in progress.* 19 pairs of casts have been digitized to date using the process described in Tasks 10a and 10b.

Task 11d Assess digitized shapes: *This task is complete.*

Task 11e Generate representative 3D models: *This task is in progress.* We investigated various 3D unwrapping techniques and how to implement them. The resulting code is used to generate 2D rectification maps. These maps can be used for identifying common modification patterns and creating templates for automated socket rectification once we have all the scanned data from Tasks 11b and 11c. We plan to create a template with Shapemaker since it uses landmarks to define the templates and this lends itself well to part of our algorithm. We can mark the trim line and quadrants, and Shapemaker can implement the lateral

rectifications. Data from the scans will describe the shape of the rectifications. Modifications to the posterior surface lack clear landmarks, hence we will need to use trends within the scans to develop an appropriate scheme for Shapemaker to use. Identifying the apex of the muscle belly in the software should be a good place to start.

Task 12 Create education materials

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13				Extension without Funds 9/15/13 to 9/14/14			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 5 Develop education materials for sub-ischial socket designs.																
Task 12 Create education materials.																
Task 12a Consult with NUPOC on the design/creation of education material.																
Task 12b Develop education material.																
Task 12c Solicit feedback on education material from prosthetists.																
Task 12d Develop plan for dissemination of education material.																

Task 12a Consult with NUPOC on the design/creation of education material: *This task is in progress.* Summarized below with Task 12c.

Task 12b Develop education material: *This task is in progress.* Summarized below with Task 12c.

Task 12c Solicit feedback on education material from prosthetists: *This task is in progress.* We have filmed and edited the casting, rectification, and fitting procedures for our sub-ischial socket for use in the instructional manual that will support dissemination of the socket to other prosthetists. However, we will need to re-film portions of the content when a new material for the flexible lamination is identified. We will then solicit feedback on the revised education material.

Task 12d Develop plan for dissemination of education material: *This task is in progress.* A pilot instructional course was presented at the 2013 World Congress of the International Society for Prosthetics and Orthotics. Portions of the course will be presented again at the 2013 ISPO Norway Seminar in October 2013 and at the 2014 American Academy of Orthotists and Prosthetists Annual Meeting.

Work on Task 12 will continue during the extension without funding.

Task 13 Final project meeting

Gantt Chart	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/15/12 to 9/14/13				Extension without Funds 9/15/13 to 9/14/14			
Progress Made Task Scheduled	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 5 Develop education materials for sub-ischial socket designs.																
Task 13 Final project meeting																
Task 13a Convene final project meeting.																

<u>Task 13a Convene final project meeting:</u> *Delayed until end of extension without funding.*

KEY RESEARCH ACCOMPLISHMENTS

- Socket fabrication and fitting techniques were transferred to prosthetists at CFI/BAMC.
- A manuscript characterizing pump performance was accepted for publication.
- Finite element analysis was completed and a manuscript prepared for publication.
- A pilot instructional course was presented at the ISPO World Congress and was well received.
- A poster describing the process for fabricating prosthetic sockets with rapid prototyping technology presented at the InNUvations Applied Research Day was awarded 3rd prize. InNUvations provides a forum for Northwestern University students to share their research with scientists, entrepreneurs and investors and explore opportunities to commercialize their product.
- Our work with socket development was highlighted in an article, “Dr. Stefania Fatone: Mixing Art and Science with P&O,” in the Center for Rehabilitation Outcomes Research newsletter in Fall 2012.
- Our work with socket development was highlighted in an article, “Socket Technology and Design: the Future of an Evolving Practice,” in O&P Business News in February 2013.
- The instructional course presented at the ISPO World Congress was highlighted in an article in the ISPO Australia e-newsletter in March 2013.
- As dissemination has continued, invitations to present about our socket are being received from different groups (e.g. Medi International, ISPO Norway, Midwest Chapter of the AAOP).

REPORTABLE OUTCOMES

Publications	Komolafe O, Wood S, Caldwell R, Hansen A, Fatone S (in press) Methods for Characterization of Mechanical and Electrical Prosthetic Vacuum Pumps. Journal of Rehabilitation Research and Development, 50(8).	Appendix E
	Komolafe O, Caldwell R, Fatone S (prepared) Finite Element Analysis of Rigid Frame Designs for Transfemoral Prosthetic Sockets.	
Abstracts	**Presented at the World Congress of the International Society for Prosthetics and Orthotics held February 4-7, 2013, Hyderabad, India:** (1) Stress Analysis of Different Rigid Frame Designs with a Flexible Transfemoral Prosthetic Socket (Oral Presentation). (2) Socket/Liner Interface Volume and Vacuum Pressure Decay in Persons with Transfemoral Amputations (Oral Presentation). (3) Characterization of Mechanical and Electrical Vacuum Pumps for Use in Vacuum-Assisted Suspension (Poster). (4) Subischial Sockets with Vacuum Assisted Suspension for Persons with Transfemoral Amputation (Instructional Course).	Abstracts were submitted with Year 2 annual report
	Presented at the 39th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium held February 20-23, 2013, in Orlando, Florida: (1) An Analytic Approach to Assessing Transfemoral Socket Flexibility (Oral Presentation). (2) Role of Socket Design, Flexibility and Suspension in Transfemoral Sockets During Walking (Poster).	Abstracts were submitted with Year 2 annual report
	Poster accepted for presentation at the Biomedical Engineering Society (BMES) Annual Meeting, September 25-28, 2013 in Seattle, Washington: Fabricating Prosthetic Sockets with Rapid Prototyping Technology (Poster).	Appendix B
	Abstract submitted for presentation at the World Congress OTWorld 2014, May 13-16, 2014, Leipzig, Germany: Clinical Outcomes Using a New Subischial Socket with Vacuum Assisted Suspension: the NU-FlexSIV.	Appendix F
Presentations	**Presented at the Monthly Veterans Research Forum, Jesse Brown VA Medical Center on March 7, 2013 in Chicago, Illinois:** A New Socket for Persons with Above Knee Amputations.	
	Presented at the Texas Association of Orthotists and Prosthetists Annual Meeting held April 19-20, 2013, in Dallas, Texas: An Analytic Approach to Assessing Transfemoral Socket Flexibility.	
	Presented at the Midwest Chapter meeting of the American Academy of Orthotists and Prosthetists, May 29-31, 2013, Lake Geneva, Wisconsin: An Analytic Approach to Assessing Transfemoral Socket Flexibility.	
	Presented at the 4th Annual Medi International Symposium, June 6-9, Mallorca, Spain: Subischial Socket Technology: Transfemoral Vacuum Concepts and Case Studies.	
	Invited to present at the ISPO Norway Seminar on "Lower Limb Socket Design and Rehabilitation", to be held on October 22-23, Oslo and Akershus University College, Norway: (1) Development of Subischial Sockets for Persons with Transfemoral Amputation. (2) Evaluation of Subischial Sockets for Persons with Transfemoral Amputation.	
	Presentation accepted at the 40th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium to be held February 26-March 1, 2014, in Chicago, Illinois: Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation.	

Posters	**9th Annual Lewis Landsberg Research Day, Northwestern University, held April 4, 2013, Chicago, Illinois:** (1) Characterization of Mechanical and Electrical Vacuum Pumps for Use in Vacuum-Assisted Suspension (Poster). (2) Fabricating Prosthetic Sockets with Rapid Prototyping Technology (Poster).	
	InNUvations Applied Research Day, Northwestern University, held May 2, 2013, in Evanston, Illinois: Fabricating Prosthetic Sockets with Rapid Prototyping Technology (poster). **(Awarded 3rd prize).**	Appendix A
	3rd Annual Musculoskeletal Research Day, Northwestern University, August 27, Chicago, Illinois: Fabricating Prosthetic Sockets with Rapid Prototyping Technology (Poster).	
People	Our post-doctoral fellow, Dr. Oluseeni Komolafe, applied for and was offered a position as a Senior Research Engineer at Medical Instill Technologies in Connecticut (a medical device company).	

CONCLUSIONS

Aims 1 & 2: A manuscript describing finite element analysis of rigid frame designs for transfemoral prosthetic sockets has been prepared and is undergoing final internal review before submission for publication. A systematic approach to evaluating the relationship between rigid frame design features and overall socket flexibility was introduced and explored. The approach was based on simulated loading of transfemoral prosthetic sockets performed using a finite element model of the prosthetic socket and residual limb. Efforts such as digital scanning for accurate representation of geometries, mechanical testing to identify material properties, and the application of experimentally measured walking loads, were made to maximize the clinical relevance of the results. The results suggest that during normal walking, maximum displacement of the rigid frames of the transfemoral sockets assessed occur after weight-acceptance events and at the onset of mid-stance. The results also confirm the use of fenestrations within the rigid frame of transfemoral prosthetic sockets to achieve flexibility. With consistently higher displacement values, the two fenestrated sockets indicate a higher flexibility compared to the completely rigid (i.e., un-fenestrated) socket.

A process for automated fabrication of prosthetic sockets has been developed. Evaluation of the resulting sockets is underway.

Aim 3: A manuscript characterizing function of existing commercial vacuum pumps was accepted for publication. We identified important pump performance metrics and developed techniques to objectively characterize the evacuation performance of prosthetic vacuum pumps. The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of two electrical (Harmony® e-Pulse and LimbLogic® VS) and three mechanical (Harmony® P2, Harmony® HD and Harmony® P3) prosthetic pumps in bench top testing. Five fixed volume chambers ranging from 3.28E-5 m^3 [2 in^3] to 1.97E-4 m^3 [12 in^3] were used to represent different air volume spaces between a prosthetic socket and a liner clad residual limb. All measurements were obtained at a vacuum pressure level of 5.76E4 Pa [17 inHg]. The proposed techniques demonstrated sensitivity to the different electrical and mechanical pumps and to a lesser degree, the different

setting adjustments of each pump. The sensitivity was less pronounced for the mechanical pumps and future improvements for testing of mechanical vacuum pumps were proposed. Overall, this study successfully offers techniques feasible as standards for assessing the evacuation performance of prosthetic vacuum pump devices.

Aim 3 Supplement: A working prototype of the hybrid vacuum pump is in development.

Aim 4: Socket fabrication and fitting techniques were transferred to prosthetists at CFI/BAMC where evaluation of the socket with service persons with amputation is underway.

Aim 5: An instructional manual has been drafted and a pilot instructional course was presented at the ISPO World Congress with additional presentations scheduled at ISPO Norway's Seminar on "Lower Limb Socket Design and Rehabilitation" in October 2013 and the American Academy of Orthotists and Prosthetists Annual Meeting in 2014. Additional revisions will be required when a new socket material has been identified.

REFERENCES

Gerschutz, MJ, Haynes, ML, Nixon, D, & Colvin, JM. (2012). Strength evaluation of prosthetic check sockets, copolymer sockets, and definitive laminated sockets. J Rehabil Res Dev, 49(3), 405-426.

McCarthy, J, Ross, J, Mcdougall, A, Ritchie, L, Ward, A, & Zahedi, S. (2013). Moisture management within a prosthetic socket. Proceedings of the World Congress of the International Society for Prosthetics and Orthotics, Hyderabad, India, February 4-7, 2013.

APPENDICES

Appendix A: Fabricating Prosthetic Sockets with Rapid Prototyping Technology (Poster)

Appendix B: Fabricating Prosthetic Sockets with Rapid Prototyping Technology (BMES Poster)

Appendix C: Chronology of Socket Pours

Appendix D: WillowWood Socket Testing Report

Appendix E: Methods for Characterization of Mechanical and Electrical Prosthetic 1 Vacuum Pumps (paper accepted at JRRD)

Appendix F: Clinical Outcomes Using a New Subischial Socket with Vacuum Assisted Suspension: the NU-FlexSIV (abstract submitted to OTWorld)

APPENDIX A

Fabricating Prosthetic Sockets with Rapid Prototyping Technology

Brian Robillard, BS, Oluseeni Komolafe, PhD, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

Northwestern University Prosthetics-Orthotics Center (NUPOC)

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

NORTHWESTERN UNIVERSITY

Background

Prosthetic socket fabrication is a time intensive process heavily dependent on the craftsmanship skill of the prosthetist. The novel subischial prosthetic socket requires an improved control over socket dimensions parameters to maximize flexibility and comfort.

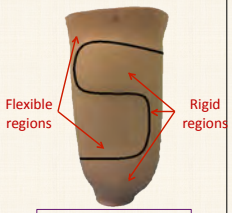
Purpose of the Study

To explore two mold orientation processes for fabricating a subischial transfemoral prosthetic socket with a flexible inner sleeve and a rigid outer frame using rapid prototyping technology.

Introduction

Manual Fabrication of Transfemoral Prosthesis

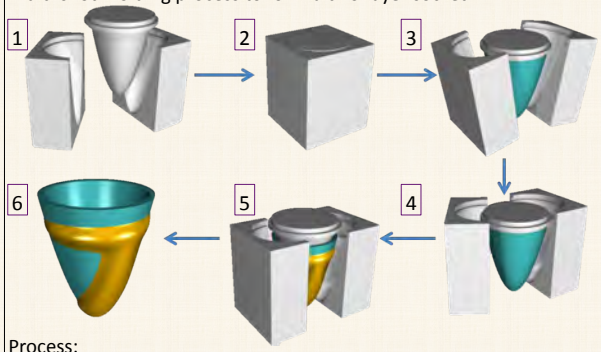
- Drawbacks:
  - Time and resource intensive
  - Requires expert prosthetist
  - Little control of socket dimension parameters (e.g. thickness)
- Fabricated socket:
  - Rigid frame sandwiched between two flexible layers



Subischial prosthetic socket

Proposed Solution (Highlighted for Horizontal Approach)

Multi-shot molding process to form a two-layer socket



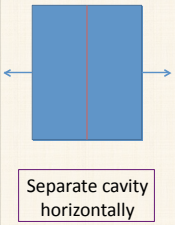
Process:

1. Inner core and inner cavity form the flexible sleeve
2. Mold is poured
3. Inner cavity is removed; inner core and sleeve remain
4. Inner core and outer cavity form the rigid frame
5. Mold is poured
6. Inner core and outer cavity are removed; socket remains

Methods/Results

1. Model design with CAD software (SolidWorks 2011)

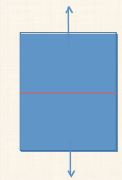
Horizontal Approach



Separate cavity horizontally

Inner core | Inner cavity | Outer cavity

Vertical Approach



Separate cavity vertically

Inner core | Inner cavity | Outer cavity

2. Fabrication in Stratasys Fortus 400mc fused deposition modeler

Horizontal Approach

Inner core | Inner cavity | Outer cavity

Vertical Approach

Inner core | Inner cavity | Outer cavity

3. Pour Process

Fabrication of flexible sleeve

Prepare molds by spraying with demolder

Clamp core and cavity; attach plastic bag to pour hole

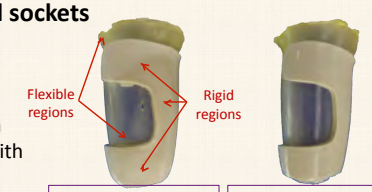
Introduce vacuum pressure to the system

Mix material* and insert into mold

*Poly PT Flex 60 for flexible layer; Smooth-Cast 385 for rigid layer

Results: Fabricated sockets

- Rigid material is heavy and brittle
- Leaking issues with horizontal approach
- Demolding issues with vertical approach



Horizontal approach | Vertical approach

Conclusions

The multi-shot molding process designed to fabricate a two-layer prosthetic socket has a demonstrated feasibility, but the process needs to be further developed in order to fabricate wearable sockets. The next steps in the design process include the following: improve mold closure, standardize pouring process, fabricate full scale socket, select new materials, and automate CAD process.

Funding Acknowledgement

Award #W81XWH-10-1-0744

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APPENDIX B

Fabricating Prosthetic Sockets with Rapid Prototyping Technology

Brian Robillard, BS, Oluseeni Komolafe, PhD, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

Northwestern University Prosthetics-Orthotics Center (NUPOC)

Northwestern University Feinberg School of Medicine

McCormick Northwestern Engineering

Biomedical Engineering

Background

The conventional process used in prosthetic socket fabrication is a time intensive, manual technique that does not allow for precise control of the resulting socket's dimension parameters and depends on the craftsmanship of highly skilled prosthetists.

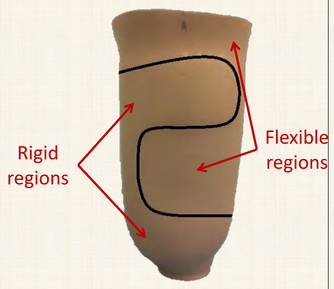
Purpose of the Study

To develop a process for fabricating a subischial transfemoral prosthetic socket with a flexible sleeve and a rigid frame using rapid prototyping technology.

Introduction

Manual Fabrication of a Transfemoral Prosthetic Socket

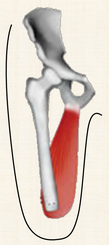
- Drawbacks:
  - Time and resource intensive
  - Requires expert prosthetist
  - Little control of socket dimension parameters (e.g. thickness)
- Socket Design
  - Rigid frame sandwiched between two flexible layers



Subischial prosthetic socket

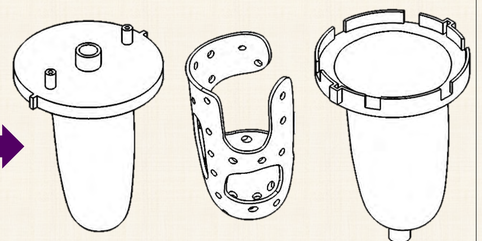
Approach Overview

1. Scan of residual limb



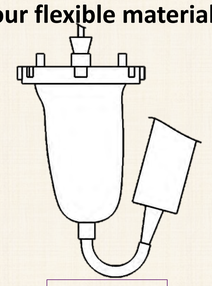
Transfemoral residual limb

2. Design with SolidWorks



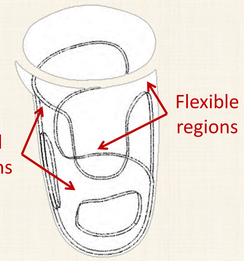
Core | Frame | Cavity

3. Build components with Stratasys and pour flexible material



Pour setup

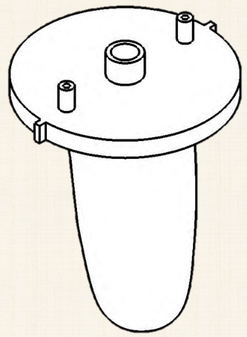
4. Fabricated Socket



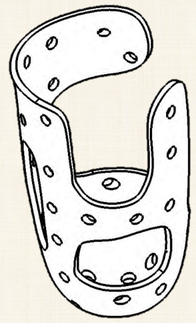
Flexible transfemoral socket

Methods/Results

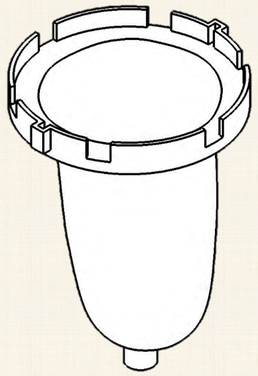
Mold design with CAD software (SolidWorks 2011)



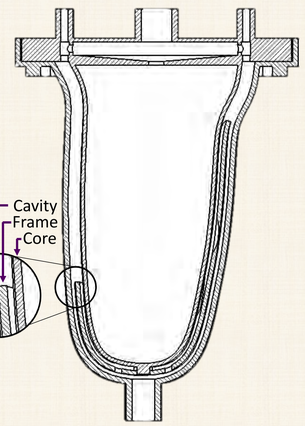
Core



Frame



Cavity



Cross section of mold setup

Fabrication in Stratasys Fortus 400mc Fused Deposition Modeler

Slice height: 0.25 mm; Build material: PC-ABS

Core

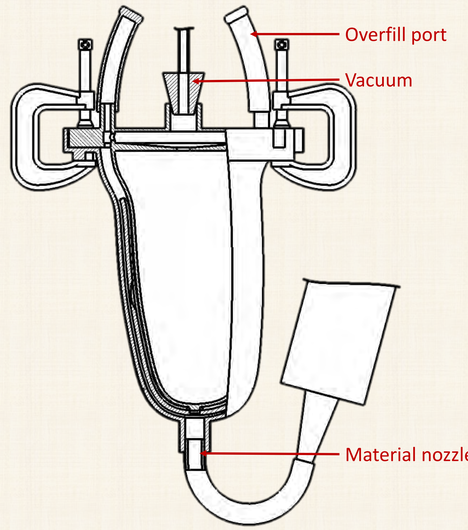
Frame

Cavity

Pour Process

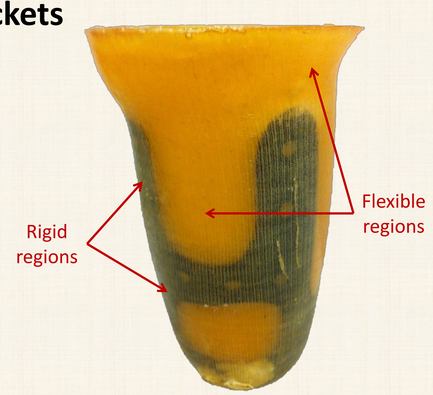
Fabrication of socket with single-shot molding technique

- Flexible material:
  - Fibre Glast Urethane Casting Resin
- Vacuum pressure:
  - Prevents air bubbles and air pockets
- Overfill ports:
  - Ensure complete saturation
- Pour time:
  - 5 minutes to pour
  - Overnight cure



Results: Fabricated sockets

- Minimal air bubbles
- Minimal air sockets
- No issues with demolding



Conclusions

The single-shot molding process designed to fabricate a two-layer prosthetic socket has demonstrated feasibility, but the socket's clinical applicability remains to be determined. The next steps in the project include the following: material and failure testing on the rapid prototyped socket with results compared to a manually fabricated socket.

Funding Acknowledgement

Award #W81XWH-10-1-0744

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APPENDIX C

Chronology of Socket Pours
Brian Robillard
September 3, 2013

Task 3: Advanced Manufacturing of sub-ischial sockets: Establish a criteria and techniques for multi-shot cavity molding

Substask 3a: We propose to mold the sockets in a cavity mold using liquid resins such as polyurethanes

Subtask 3b: Develop degassing techniques for liquid resin molding

Subtask 3d: Develop mechanical interlock molding techniques

Socket 1	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: Smooth-Cast 385	- Vacuum pour - Multiple holes on inner core proximal end	- No mechanical interlocking attempted - Material adhesion was poor	- Filled from distal end - Distal end pointing down

Socket 2	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: PC-ABS T16 tip	- Vacuum pour - Multiple holes on inner core proximal end	- 4 holes on distal end of frame	- Filled from distal end - Distal end pointing up

Socket 3	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: ABS M30 T16 tip	- Vacuum pour - Multiple holes on inner core proximal end	- Dozens of hole on frame - Frame sandwiched between fabric	- Filled from distal end - Distal end pointing down - Holes on inner core were stuffed with paper towels

Socket 4	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: ABS M30 T16 tip	- No vacuum - Two holes on inner core proximal end - Holes on distal end of cavity to allow air to escape	- Dozens of hole on frame - Frame sandwiched between fabric - Triangular extrusion	- Filled from distal end - Distal end pointing up

Socket 5	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: ABS M30 T16 tip	- No vacuum - No holes proximal end - Holes on distal end of cavity to allow air to escape - Distal end of cavity thickened to allow material to flow and air to escape	- Dozens of hole on frame - Frame sandwiched between fabric - Triangular extrusion	- Filled from distal end - Distal end pointing up - Poured with nozzle on distal end that allowed air to escape from distal tip

Socket 6	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: ABS M30 T16 tip	- Vacuum pour - Two holes on proximal end of inner core	- Dozens of hole on frame - Frame sandwiched between fabric - Triangular extrusion	- Filled from distal end - Distal end pointing up

Socket 7	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: PC-ABS T16 tip	- Vacuum pour - Two small holes on proximal end of inner core	- Dozens of hole on frame - Frame sandwiched between fabric - Triangular extrusion	- Filled from distal end - Distal end pointing down

Socket 8	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: PC-ABS T16 tip	- Vacuum pour - Two small holes on proximal end of inner core	- Dozens of hole on frame - Frame sandwiched between fabric	- Filled from distal end - Distal end pointing down - Hexagonal extrusion

Socket 9	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Polytek Poly PT Flex 60 Rigid: PC-ABS T16 tip	- Vacuum pour - Two small holes on proximal end of inner core	- Dozens of hole on frame - Frame sandwiched between fabric	- Filled from distal end - Distal end pointing down - Overfill ports - Hexagonal extrusion

Socket 10	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Urethane Casting Resin 60 Shore A Rigid: PC-ABS T16 tip	- Vacuum pour - Two small holes on proximal end of inner core	- Dozens of hole on frame - Frame sandwiched between fabric - Triangular extrusion	- Filled from distal end - Distal end pointing down - Forgot the overfill ports - Hexagonal extrusion

Socket 11	Subtask 3a notes	Subtask 3b notes	Subtask 3c notes	Orientation/vacuum/notes
	Material used: Flexible: Urethane Casting Resin 60 Shore A Rigid: PPSF T16 tip	- Vacuum pour - Two small holes on proximal end of inner core	- Dozens of hole on frame - Frame sandwiched between fabric - Triangular extrusion	- Filled from distal end - Distal end pointing down - Hexagonal extrusion

APPENDIX D

WillowWood
15441 Scioto Darby Road
P.O. Box 130
Mt. Sterling, OH 43143

TEST: AK SOCKET EVALUATION
DATE: 11/5/2012

SUBJECT: Evaluate the static strength of AK prosthetic sockets using a modified ISO 10328 Configuration II A125 test set-up

TESTING NOTES:

(1) The sockets were arbitrarily labeled NU-1, NU-2 and NU-3.

(2) All three sockets fitted the test model well. No visual presence of gapping or non-distal contact.

(3) Socket measurements were collected prior to testing. Measurements were taken in relatively the same location on each socket.

	Socket ID		
	NU-1	NU-2	NU-3
A1	7.85	8.20	7.60
A2	4.40	3.65	4.30
A3	7.85	7.25	6.90
A4	4.50	3.70	4.30
M1	7.30	6.70	7.90
P1	3.50	4.35	3.70
P2	3.30	4.30	3.20
L1	4.45	5.00	4.35

General Notes
Measurements were take in the same relative area.

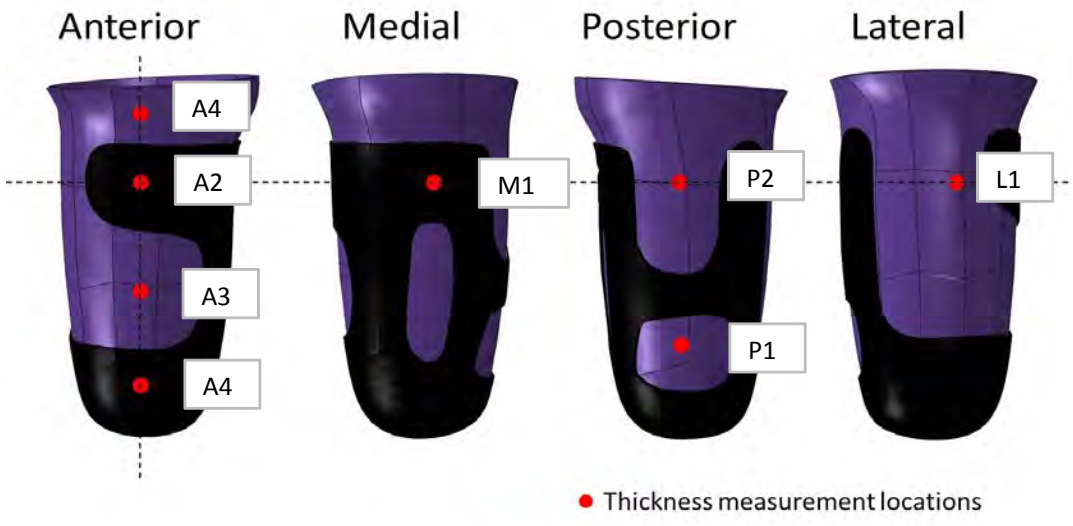

Figure 1: Thickness Measurements

WillowWood
15441 Scioto Darby Road
P.O. Box 130
Mt. Sterling, OH 43143

TEST: AK SOCKET EVALUATION
DATE: 11/5/2012

TEST PARAMETERS: The static test was conducted in accordance with ISO 10328 Configuration II A125 with the anterior in tension and posterior in compression. The sockets were tested to failure.

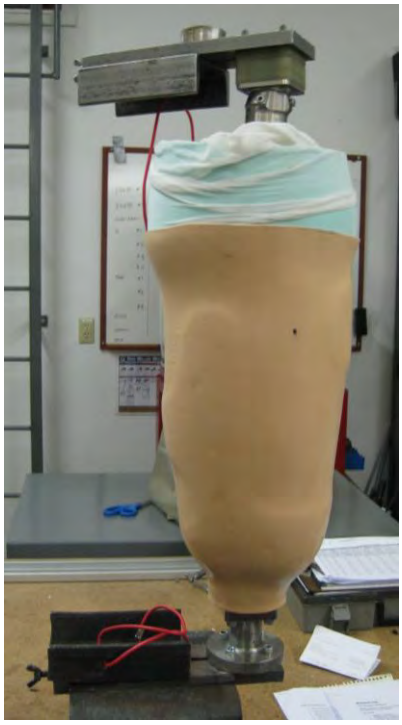

Figure 2: Socket set-up

RESULTS: All three sockets failed at the distal adapter location. The distal adapter was pulled out of the socket. For two of the sockets (NU-2 and NU-3), the distal adapter pulled completely out of the socket.

Figure 3: NU-1 distal adapter failure

Figure 4: NU-2 distal adapter failure

Figure 5: NU-3 distal adapter failure

Even though it is not visible in the video, one of the test technicians commented that the distal posterior area (close to P1 on the thickness measurements) exhibited a buckling effort. The soft structural material in this area flexed upon itself. Pictures below indicate the effects upon this area. A slight crease was visible on the exterior and interior of the socket.

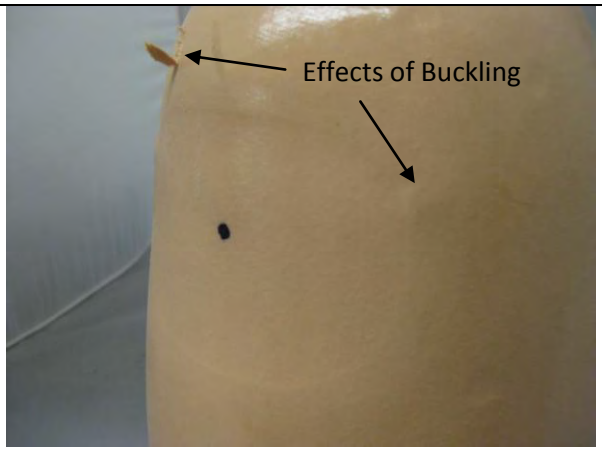

Figure 6: NU-2 Posterior portion after testing

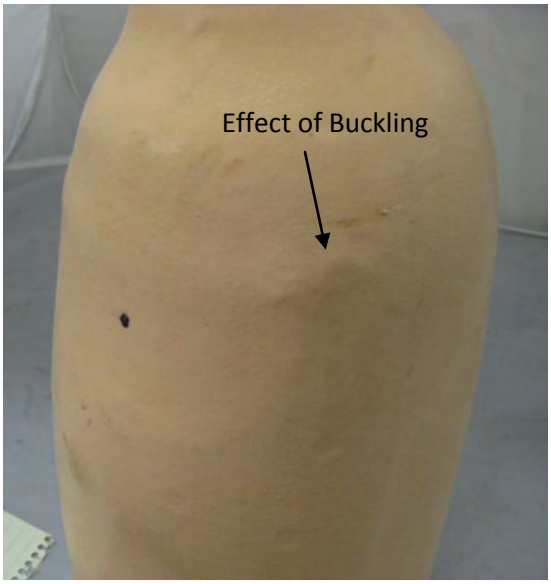

Figure 7: NU-3 Posterior portion after testing

The force deflection curve for all three sockets is provided below. The yield strength and compression point were determined from the force deflection curves. Yield strength was defined as the location where plastic deformation occurs (location where the initial linear characteristic portion of the curve deviates). The yield strength was used in a previous study to evaluate sockets that failed in a ductile mode. The compression point is either a deformation peak or plateau change after the initial linear portion of the curve. The compression point was used in a previous study to evaluate sockets that failed in brittle mode. The ISO 10328 Configuration II A125 passing criteria for brittle failure is 4426 N and for ductile failure is 3421N. Prosthetic sockets are not subjected to any standard including ISO 10328. ISO 10328 is intended for structural components that would normally be attached to a socket. Visually, the sockets exhibited some ductile characteristics by deforming prior to breaking. The force deflection curves for the tested sockets also displayed this slight tendency towards a ductile failure. The curves illustrated a small deformation after the linear portion of the curve prior to a peak or plateau change. NU-1 exhibited more of a distinct peak than the other two sockets. The displacement range for all three sockets were similar to the carbon transtibial sockets tested in another study. Previously tested transtibial carbon sockets were classified as having brittle failures.

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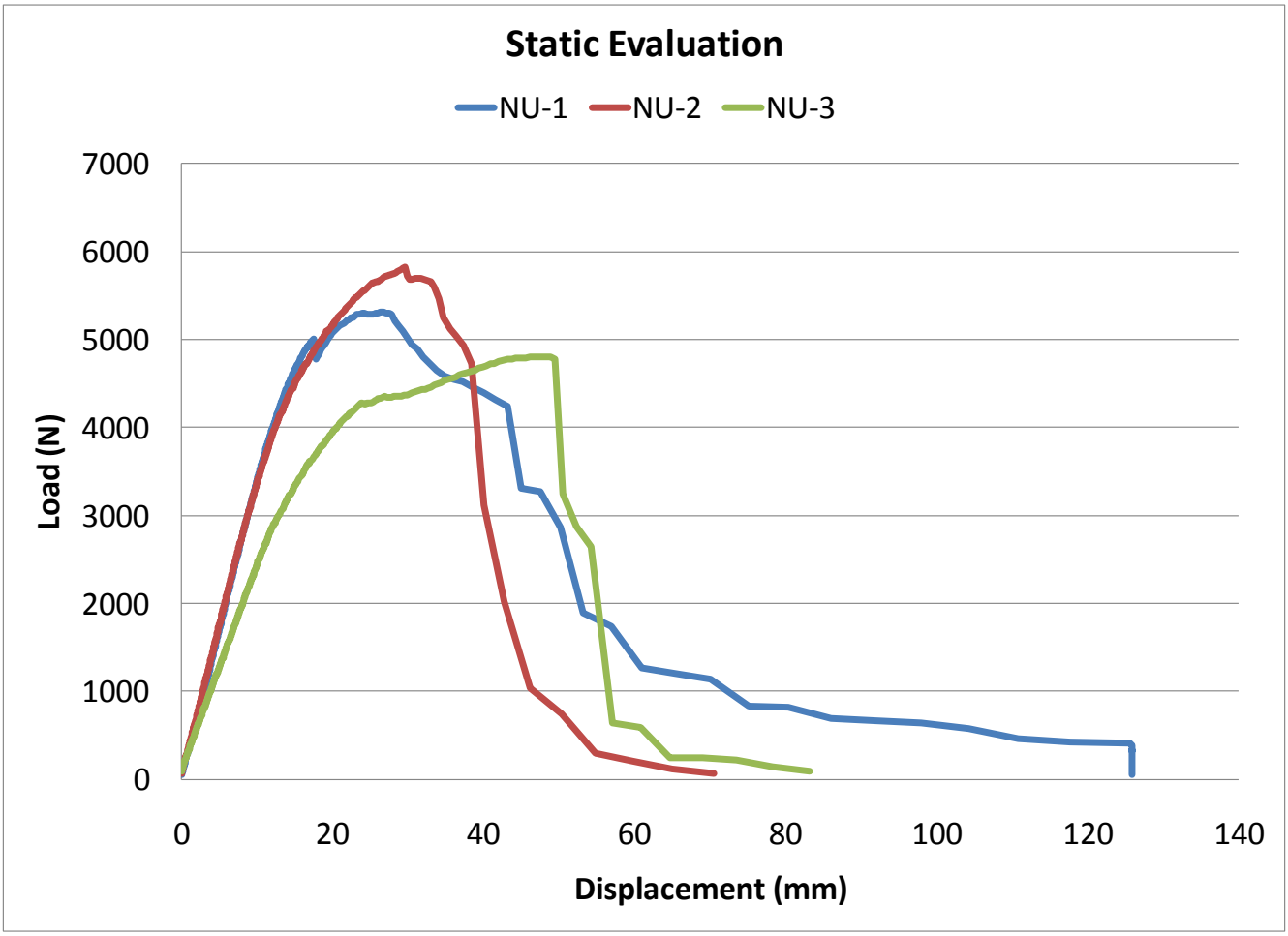
TEST: AK SOCKET EVALUATION
DATE: 11/5/2012



	Yield Strength (Inflection Point)		Compression Point (Deformation Peak or Plateau Change)	
	mm	N	mm	N
NU-1	13.02	4240.93	17.41	5005.49
NU-2	12.28	3978.11	29.62	5817.83
NU-3	13.69	3141.87	23.81	4276.77
	Ave	*3786.97*	*Ave*	*5033.36*
	Stdev	*573.92*	*Stdev*	*770.908*

Supplementary Information:

Video: Socket 1 video; Socket 2 video; Socket 3 video

Pictures: Socket 1_1 to Socket 1_3; Socket 2_1 to Socket 2_8; Socket 3_1 to Socket 3_8

15441 Scioto Darby Road
P.O. Box 130
Mt. Sterling, OH 43143

APPENDIX E

Characterization of Mechanical and Electrical Prosthetic Vacuum Pumps

Journal:	*Journal of Rehabilitation Research & Development*
Manuscript ID:	JRRD-12-11-0204.R1
Manuscript Subtype:	Technical Reports
Date Submitted by the Author:	16-Jan-2013
Complete List of Authors:	Komolafe, Oluseeni; Northwestern University, Physical Medicine and Rehabilitation Wood, Sean; Space Exploration Technologies, Avionics Caldwell, Ryan; Northwestern University, Physical Medicine and Rehabilitation Hansen, Andrew; Minneapolis Veterans Affairs Health Care System, Engineering Research Program; University of Minnesota, Physical Medicine and Rehabilitation Fatone, Stefania; Northwestern University, Physical Medicine and Rehabilitation
Keywords:	Electrical prosthetic pump, Elevated vacuum, Mechanical prosthetic pump, Negative pressure, Prosthetic pump, Prosthetic pump performance, Prosthetic vacuum, Socket evacuation, Vacuum assisted suspension, Vacuum pump

JRRD at a Glance

Prosthetic vacuum pumps generate high levels of vacuum pressure that are used to secure prosthetic sockets onto the residual limb of persons with amputations. Despite their increasing use in clinical practices, there are only a few guidelines directing the prosthetist's and user's selection among alternative vacuum pumps. These guidelines are primarily limited to manufacturer specifications. This report describes techniques developed to assess the performance of prosthetic vacuum pumps and demonstrates those techniques using a number of commercially available electrical and mechanical pumps. The findings may contribute to clinicians' judgments on appropriate componentry for their patients needs.

Title: Methods for Characterization of Mechanical and Electrical Prosthetic Vacuum Pumps

Authors

Oluseeni Komolafe, PhD[1], Sean Wood, MS[2], Ryan Caldwell, CP[1], Andrew Hansen, PhD[3,4] and Stefania Fatone, PhD, BPO(Hons)[1]

[1]Northwestern University Prosthetics-Orthotics Center, Chicago IL; [2]Space Exploration Technologies, Hawthorne, CA; [3]Minneapolis VA Health Care System, Minneapolis, MN; [4]University of Minnesota, Minneapolis, MN

Funding source

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Corresponding Author

Oluseeni Komolafe, PhD

Northwestern University Prosthetic Orthotic Center

680 N Lake Shore Drive, Suite 1100

Chicago IL 60611

Phone: (312) 503-5728. Fax: (312) 503-5760

Email: o-komolafe@northwestern.edu

Abstract

Despite increasingly widespread adoption of vacuum assisted suspension systems in prosthetic clinical practices, there remain gaps in the body of scientific knowledge guiding clinicians' choices of existing products. In this study, we identified important pump performance metrics and developed techniques to objectively characterize the evacuation performance of prosthetic vacuum pumps. The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of two electrical (Harmony® e-Pulse and LimbLogic® VS) and three mechanical (Harmony® P2, Harmony® HD and Harmony® P3) prosthetic pumps in bench top testing. Five fixed volume chambers ranging from 3.28E-5 m^3 [2 in^3] to 1.97E-4 m^3 [12 in^3] were used to represent different air volume spaces between a prosthetic socket and a liner clad residual limb. All measurements were obtained at a vacuum pressure level of 5.76E4 Pa [17 inHg]. The proposed techniques demonstrated sensitivity to the different electrical and mechanical pumps and to a lesser degree, the different setting adjustments of each pump. The sensitivity was less pronounced for the mechanical pumps and future improvements for testing of mechanical vacuum pumps were proposed. Overall, this study successfully offers techniques feasible as standards for assessing the evacuation performance of prosthetic vacuum pump devices.

Key Words

Electrical prosthetic pump, elevated vacuum, mechanical prosthetic pump, negative pressure, prosthetic pump, prosthetic pump performance, prosthetic vacuum, socket evacuation, vacuum assisted suspension, vacuum pump.

Abbreviations

Lithium-ion - Li-Ion; Vacuum Assisted Suspension – VAS; International Organization for Standardization - ISO

Introduction

Prosthetic suspension refers to the mechanism by which the prosthetic socket is secured onto the residual limb of a person with an amputation, with poor suspension resulting in relative motion between the prosthetic socket and residual limb [1]. Vacuum assisted suspension (VAS) of prosthetic sockets uses electrical or mechanical pumps to create a negative pressure differential (i.e. vacuum) between the interior of a prosthetic socket and the surface of a liner clad residual limb. Since its introduction and adoption in the late 1990's, investigations of VAS have focused on lower limb prosthetic applications and the effects of vacuum on residual limb volume [2-5], socket suspension [2], socket fit and interface pressures [6, 7], gait kinematics, and residual limb health [8, 9]. These studies suggested VAS improved the limb health of prosthesis users by minimizing trauma-inducing relative motion between the socket and residual limb, as well as by promoting tissue hydration, evidenced by reduction in fluctuations in residual limb volume. The high numbers of reports in related professional journals[1,2] as well as in prosthetic trade magazines[3,4] suggest an increasingly widespread use of VAS in prosthetic clinical practice as well as a concomitant increase in the number of commercially available pumps for achieving

---

[1] Street, G., Vacuum Suspension and its Effects on the limb. Orthopädie Technik, English Edition 2006. **IV**(English Edition): p. 1-6.

[2] Brunelli, S., Vacuum Assisted Socket System in Transtibial Amputees: Clinical Report, in Orthopädie Technik, English Edition 2009: Germany. p. 2-8.

[3] Patterson, S, Experiences with Negative-Pressure Socket Design, in The Academy Today 2007. p. A7-9.

[4] Fairley, M., 'Hanging Tight': Elevated Vacuum Suspension Systems Step Forward, in The O&P Edge March 2008.

VAS in prosthetic socket systems. However, other than manufacturer specifications, the authors have no knowledge of any guidelines in the way of standardized pump performance characterization that may assist clinicians' decision making. This is in contrast to the large number of characterization studies on other commercially available prosthetic devices and components such as prosthetic feet [10, 11], shock absorbing pylons [12, 13], prosthetic knees [14, 15], liners and interface materials [16-18].

Hence, the purpose of this study was to develop techniques to characterize the performance of prosthetic vacuum pumps. Important performance metrics considered included the pumps' evacuation rates to specific vacuum levels and maximum evacuation capabilities under standardized protocols. The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of several commercially available electrical and mechanical pumps.

Methods

Equipment

Based on input from a certified prosthetist (author RC) regarding their level of use in prosthetic practice, two electrical (Harmony® e-Pulse and LimbLogic® VS) and three mechanical (Harmony® P2, Harmony® HD and Harmony® P3) prosthetic pumps (Table 1) were purchased and their evacuation performance evaluated. In both electrical pumps, a Lithium-ion (Li-Ion) battery powered a DC motor, which ran a small capacity pump. Microprocessor circuitry within the pump monitored the vacuum pressure in the prosthetic socket system and reactivated the pump if the vacuum pressure level decreased below a prescribed threshold.

The three mechanical pumps were designed to be installed in-line with the prostheses and engaged the weight of the user to generate vacuum pressure through two distinctly different

activation mechanisms. The two "piston actuated" mechanical pumps (Harmony® P2 and Harmony® HD) pulled air from the socket to the pump chamber during stance phase on the prosthetic limb while walking (i.e., when the prosthesis was loaded). The pumps could be configured for different user weights through adjustments of the tension of an elastomer rod within the pumps (Table 2). Conversely, the "compressible bladder" mechanical pump (Harmony® P3) pulled air from the socket to the pump bladder during swing phase of the prosthetic limb while walking (i.e., when the prosthesis was unloaded). In this case, the pump was configured for different user weights using bladders of varying resistance to compression (i.e., functional rings denoted "0" to "4" in order of increasing resistance in Table 2). In both mechanisms, air was pushed out from the pump chamber during the alternate phase of walking, i.e., during swing phase for the piston actuated pumps and during stance phase for the compressible bladder pump.

For the purpose of this study, a well fitted sub-ischial prosthetic check socket was fabricated for an average sized male subject with a transfemoral amputation. The air volume space between the inner surface of the doffed check socket and an appropriately sized liner was estimated at 9.83E-5 m^3 [6 in^3] based on previous characterization of the evacuation time of the LimbLogic® VS pump. Scaling about this reference, five fixed volume chambers were manufactured from polyvinyl chloride (PVC) tubing and end-caps (ranging from 3.28E-5 m^3 [2 in^3] to 1.97E-4 m^3 [12 in^3]). These chambers were used during evacuation testing of the prosthetic pumps to simulate varying air volume spaces of transfemoral sockets, although the range of volumes, in particular the smaller volumes, may also be relevant to transtibial sockets. Exact volumes of the chambers were calculated by dividing the weight of the mass of water required to fill the chambers by the density of water.

A servo-hydraulic materials testing system (Instron 8800 Controller, MA, U.S.A.) was used to apply periodic vertical loads, representative of a prosthesis user's weight during walking, to the mechanical pumps. For both electrical and mechanical pump systems, vacuum pressure measurements were acquired using a digital vacuum pressure gauge (DIGIVAC model 2L760, New Jersey, U.S.A.) with a detection resolution of 2.70E2 Pa [0.08 inHg]. The gauge was customized to a full scale output of 5V at the baseline pressure of the testing environment (e.g. at sea-level, the full scale voltage would correspond to the standard average atmospheric pressure of 1.01E5 Pa [29.92 inHg]). Prior to each testing session, the gauge was calibrated for a measurement span of negative 8.47E4 Pa [-25 inHg], relative to the baseline pressure. For simplicity, the negative sign on the vacuum pressure levels will be omitted in the remainder of this report.

Experimental Procedures

Electrical pump testing

The setup for the performance testing of the two electrical pumps consisted of connecting each pump to one of the five fixed volume chambers using airflow tubing (Figure 1). The pump was activated and the vacuum pressure within the connected chamber was monitored and recorded. After evacuation to a specified vacuum level, the airflow tubing was disconnected to return the chamber to the baseline pressure. This process was repeated for five trials of each electrical pump and chamber combination.

Preliminary assessment of the out-of-box capabilities of the two electrical pumps in this study indicated the maximum vacuum pressure level common to both pumps was 5.76E4 Pa [17 inHg]. Consequently, for each chamber, the "evacuation time" of both electrical pumps, was defined as

the total time from initial pump activation (start-time) to achieving a vacuum pressure of 5.76E4 Pa [17 inHg] in that chamber (end-time).

The discovery of inconsistent evacuation times for the electrical pumps over consecutive days suggested the performance of the pumps was dependent on level of battery charge. Accounting for this dependency by performing all evacuations with the pumps connected to an AC power supply was not possible because the Harmony® e-Pulse pump was unable to be simultaneously activated and charged. Instead, a series of exhaustive tests (i.e., testing each pump to complete battery charge depletion) were performed to quantify the dependence of both pumps' evacuation performance on battery discharge. The exhaustive testing for each pump involved evacuating the 9.83E-5 m^3 [6 in^3] chamber repeatedly to 5.76E4 Pa [17 inHg], allowing only time to return the chamber to the baseline atmospheric pressure between each evacuation trial, until the Li-Ion battery of the pump was depleted.

Mechanical pump testing

The performance of the two piston actuated mechanical pumps (Harmony® P2 and Harmony® HD) were assessed at three different settings of manufacturer prescribed elastomer rod tension adjustments, while the performance of the compressible bladder mechanical pump (Harmony® P3) was assessed for the five weight-rated functional rings (Table 2). Prior to testing, each functional ring was "pre-compressed" for 15 minutes using a compression tool provided by the manufacturer[5] and allowed to equilibrate to the testing temperature and humidity environment for a minimum of 24 hours before testing. To simulate the *in-vivo* compressive cyclic loads exerted on the pumps during walking, the pumps were loaded using the hydraulic piston ram of

[5] Otto-Bock-HealthCare-LP, Harmony P3 Instructions for Use, 2009: United States of America.

the material testing system. Airflow tubing was used to connect the installed pumps to the fixed volume chambers and the digital vacuum pressure gauge (Figure 1).

The piston ram was configured to compress the two piston actuated pumps by 0.007 m, at a cyclic loading rate of 0.023 m/sec and the compressible bladder pump by 0.005 m at the same cyclic loading rate. These values represent the manufacturer's displacement recommendations for optimal pump performance[6] and an approximate prosthetic limb cadence of 100 steps per minute, with a 50:50 proportion of single and double limb stance support. The numbers of loading-unloading cycles applied to each mechanical pump were determined from pilot data and identified as the number of cycles at which continued activation of the pumps created a negligible increase in vacuum pressure. Consistently for all pump weight settings and chamber combinations, three trials of 200 loading-unloading cycles were applied to the piston actuated pumps and three trials of 300 loading-unloading cycles applied to the compressible bladder pump.

Data Analysis and Calculations

The vacuum pressure data generated by the mechanical pumps exhibited a step-like profile, increasing as the pumps were loaded and staying approximately constant upon removal of load. The data were resampled to isolate the vacuum pressure value at the start of the loading-unloading cycle, effectively decimating the data to a single data point per cycle. Unlike the electrical pumps, where the maximum vacuum pressures were controlled by microprocessor

[6] Otto-Bock-HealtCare-LP, Harmony P2 and Harmony HD Instructions for Use, 2004: United States of America.

circuitry, the maximum vacuum pressures generated by the mechanical pumps were potentially dependent on the number of cyclic activations of the pumps. In an attempt to address this dependence, a theoretical maximum vacuum capacity was calculated and reported for each mechanical pump. This calculation involved a linear extrapolation of the terminal region of the asymptotic trending vacuum pressure data to three times the total testing duration of that trial. For all electrical and mechanical pump trials, the evacuation times to a vacuum pressure of 5.76E4 Pa [17 inHg] were measured and averaged over the number of repeated trials for all pump, setting and chamber combinations.

Results

Electrical Pump Testing (Table 3, Figures 2 and 3)

Exhaustive testing of the electrical pumps demonstrated the Harmony® e-Pulse had a total of 178 evacuations before complete battery depletion, with a 14% increase in time to evacuate to 5.76E4 Pa [17 inHg] over the entire course of the test. We noted a distinct change in the time to evacuate between the first 104 trials and the subsequent 75 trials, with consistent evacuation times within each group of trials (standard deviation of 0.40 and 0.54, respectively). By comparison, the LimbLogic® VS achieved a total of 225 evacuations using only half a full battery charge (as indicated by the pump battery meter) before exhaustive testing was terminated. There was a 2.4% total increase in evacuation time to 5.76E4 Pa [17 inHg] over the course of the test.

The average time to evacuate all five chambers to 5.76E4 Pa [17 inHg] for the LimbLogic® VS was 11.57 seconds, while the Harmony® e-Pulse required 18.04 seconds (56% more time) to evacuate the same chambers. For both electrical pumps, linear equations were able to describe

most of the variability in the evacuation times as a function of the five chamber volumes (R^2 > 0.99). The best-fit lines of evacuation times plotted against chamber volume showed the LimbLogic® VS had a smaller slope compared to the Harmony® e-Pulse despite having a similar y-intercept.

Mechanical Pump Testing (Table 4, Figure 4)

Across the three manufacturer prescribed elastomer rod tension settings and for the same chamber volumes at those settings, neither the Harmony® P2 or Harmony® HD pumps showed substantial differences in their evacuation times to 5.76E4 Pa [17 inHg], the number of activation cycles required, nor their theoretical maximum vacuum capacity. The Harmony® P3 pump showed a consistent trend of increasing evacuation times to 5.76E4 Pa [17 inHg], increasing number of activations required and a decreasing theoretical maximum vacuum capacity with increasing resistance to compression (i.e., functional rings denoted "0" to "4").

A comparison of the maximum forces exerted by the hydraulic piston ram during application of the programmed compressive displacement to the Harmony® P2 and Harmony® HD pumps showed no sensitivity to the chamber volume within the three elastomer rod settings. However, across the three settings, there were clear differences, generally trending, with the exception of results of setting 1 of the Harmony® P2 pump, to increasing maximum force with increasing resistance to compression of the elastomer rod. The Harmony® P3 pump performed with less consistency within and across the different resistance to compression.

Discussion

The purpose of this study was to develop techniques to characterize the performance of vacuum pumps intended for clinical application within prostheses. Such characterizations offer insights to

guide clinicians' selection of devices and components. To assess the sensitivity of the proposed techniques, several commercially available vacuum pumps were characterized in a series of bench top tests.

Electrical Pump Battery Depletion Testing

Results of the exhaustive battery testing indicated a slight increase in evacuation time over sequential trials, suggesting a dependence of pump performance on total battery charge. The substantially higher number of total evacuations of the LimbLogic® VS pump compared to the Harmony® e-Pulse was likely due to the quality of the battery and other components of the pumps. In spite of the dependence, both pumps performed consistently over approximately the first 100 trials on the 9.83E-5 m^3 [6 in^3] chamber volume. As a limitation to the generalizability of these results, the proposed technique did not assess the energy usage of the different pumps in their "stand-by," pressure monitoring modes. Conceivably, this may be the primary pump power state within well-fitted non-leaky socket systems and therefore may be the primary driver of energy consumption by the pumps.

Electrical Pump Testing

Selection of 5.76E4 Pa [17 inHg] as a standard vacuum pressure level for measuring evacuation time was driven by preliminary assessment to determine the maximum vacuum pressure level common to both electrical pumps. Studies investigating the appropriate vacuum pressure levels for VAS generally suggest higher vacuum levels are preferred by prostheses users[7]. However, there remains little evidence or consensus at to the appropriate vacuum levels to be used in VAS.

[7] M.J. Gerschutz, .J.A.Denune, J.M. Colvin, G. Schober, M.L. Haynes, D. Nixon, Technical Notes on Elevated Vacuum Suspension: Amputee Patient Outcomes Evaluating Patient Verbal Opinion and Pressure Data, Ohio Willow Wood.

The LimbLogic® VS consistently outperformed the Harmony® e-Pulse in time to evacuate each chamber, averaging 56% less time to achieve a vacuum level of 5.76E4 Pa [17 inHg] (Figure 3). For both pumps, linear equations were able to describe most of the variability in evacuation times as a function of the different chamber volumes. Despite having similar y-intercepts, the LimbLogic® VS had a smaller slope compared to the Harmony® e-Pulse pump, suggesting a higher base functional performance because increases in volumes resulted in smaller increases in evacuation time.

Mechanical Pump Testing

Our decision to adopt a bench-top approach to characterizing the performance of the mechanical pumps allowed precise control of the loading variables. The pumps were actuated by the servo-hydraulic materials testing system using a displacement control paradigm. The amount of compression of the pumps, the cyclic loading rate, and the total number of loading-unloading cycles were determined prior to initiation of the test.

At the three weight settings tested for the Harmony® P2 and Harmony® HD pumps, there were no differences in pump performance within, as well as across, both pumps (Table 4, Figure 4). This finding incorrectly suggested the different elastomer rod tension adjustments had no effect on pump performance. Correct interpretation required consideration of the control paradigm used for loading of the mechanical pumps. Under a displacement controlled paradigm, the testing system adjusted the force applied at each weight setting to achieve prescribed displacements. We expected the applied force to increase with increasing resistance (i.e., setting $1 < 4 < 6$) for both pumps. The results (Figure 4), with the inexplicable exception of the Harmony® P2 pump at setting 1, followed these trends and demonstrated sensitivity of the pump performance to the different settings.

As previously described, the Harmony® P3 pump used compressible bladders (functional rings) to pull air from the socket and generate vacuum pressure. With increasing resistance of the functional rings (from ring 0 to 4), the time and number of cyclic activations required to achieve 5.76E4 Pa [17 inHg] for each chamber also increased. Conversely, the theoretical maximum vacuum capacity reduced. These results suggested the mechanism used to increase resistance was increased wall thickness of the bladders, effectively reducing the total volume of the bladders. Hence, with the stiffer bladders, the amount of air moved by the pump per activation cycle was reduced.

There are limitations to this study that curtail the scope and generalizability of our findings. First, a single pump of each type was used to assess the techniques presented in this report. Results of such a small sample are not generalizable to all pumps of the same type; however, several precautions were taken to mitigate errors introduced by the use of single samples. Both electrical pumps had less than 10 hours of use, primarily usage for preliminary evaluation, at commencement of our tests. Similarly, the three mechanical pumps had been exposed to very limited use at the start of data collection. Brand new functional rings were purchased for the Harmony® P3 pump and pre-compressed according to manufacturer recommendations. These precautions allow the reasonable assumption that all pumps, batteries and components remained true to their original technical specifications.

Second, the two piston actuated mechanical pumps required only *one* end of the pump be attached to the testing system (Figure 1A and 1B) during the loading (i.e., pump compression) phase of the actuation cycle. Upon removal of load, the elastomer tension rods' restorative forces *passively* returned the pumps to their uncompressed heights. This approach worked well for the two piston actuated pumps; however, the restorative force of the compressible bladder pump was

not sufficient to return the Harmony® P3 to its original, uncompressed height in the time allowed by the loading-unloading rates tested in this study.

As the number of actuation cycles increased, the pump height gradually decreased until all evacuation functioning ceased due to the compressed bladder, i.e. a “bottoming out” of the bladder. Our solution was to attach ***both*** ends of the pump to the materials testing system (Figure 1C). This introduced a ***forcible***, as opposed to a passive restoration to the original bladder pump height during the unloading phase of the actuation cycle. Care was taken to ensure the compressible bladder pump was returned only to its uncompressed height, with negligible off-axial forces applied to the bladder while unloading.

In normal usage, a possible source of restorative force is the weight of prosthetic components distal to the pump during the swing phase of the prosthetic limb. As this weight is typically small, the resulting restorative force is expected to be negligible. Since the loading-unloading rate tested in this study was based on reported estimates, we expect the Harmony® P3 pump to experience a bottoming out effect, and the actual performance, particularly regarding the maximum vacuum capacity, to be worse in clinical use than our results suggest.

Finally, the estimate of the air volume space between the prosthetic socket’s inner surface and the outer surface of the liner clad residual limb was obtained from the socket of an average sized male with a transfemoral amputation. However, the use of different fixed volume canisters spanning a large range of air space volumes, including the volumes of smaller transtibial prosthetic sockets, extended the generalizability of the results.

The testing of the mechanical pumps could be improved by use of machines for ISO 22675 testing[8]. ISO 22675 testing machines are designed to test prosthetic feet in a heel to toe loading fashion that simulates walking. These machines also utilize force control to mimic the ground reaction forces during walking. Mechanical pumps could be placed in line with pylons and feet within these testing machines to obtain more realistic results. Manufacturers of mechanical vacuum pumps for use in prostheses could use similar metrics as described in this paper, but with improved loading from ISO 22675 machines.

Conclusion

There are presently no guidelines nor standardized characterization methods to assist clinicians' when deciding among existing choices of prosthetic vacuum pumps. The proposed techniques were used to characterize the evacuation performance of several commercially available electrical and mechanical pumps. The assessment metrics demonstrated sensitivity to the different electrical and mechanical pumps and to a lesser degree, the different settings of each pump. Overall, this study offers techniques feasible for general adoption as standards for assessing the evacuation performance of electrically controlled and mechanical prosthetic vacuum pumps.

[8] ISO. ISO 22675:2006: Testing of ankle foot devices and foot units -- Requirements and test methods. Prosthetics [Standard] 2006 2006-09-14; 92]. Available from: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=36413

References

1. Kapp, S., *Suspension systems for prostheses.* Clinical Orthopaedics and Related Research, 1999(361): p. 55-62.
2. Board, W.J., G.M. Street, and C. Caspers, *A comparison of trans-tibial amputee suction and vacuum socket conditions.* Prosthet Orthot Int, 2001. **25**(3): p. 202-9.
3. Goswami, J., et al., *Walking in a vacuum assisted socket shifts the stump fluid balance.* Prosthet Orthot Int, 2003. **27**(2): p. 107-13.
4. Gerschutz, M., Denune, JA, Colvin, JM, Schober, G *Elevated Vacuum Suspension Influence on Lower Limb Amputee's Residual Limb Volume at Different Vacuum Pressure Settings.* Journal of Prosthetics and Orthotics, 2010. **22**(4): p. 252-256.
5. Sanders, J.E., et al., *Effects of elevated vacuum on in-socket residual limb fluid volume: case study results using bioimpedance analysis.* J Rehabil Res Dev, 2011. **48**(10): p. 1231-48.
6. Beil, T.L., G.M. Street, and S.J. Covey, *Interface pressures during ambulation using suction and vacuum assisted prosthetic sockets.* J Rehabil Res Dev, 2002. **39**(6): p. 693-700.
7. Gerschutz, M., *Elevated vacuum suspension: Evaluation of residual limb movement in a prosthetic socket*, in *American Academy of Orthotists and Prosthetists, 36th Annual Meeting and Scientific Symposium* 2010: Chicago, IL.
8. Traballesi, M., et al., *Trans-tibial prosthesization in large area of residual limb wound: is it possible? A case report.* Disabil Rehabil Assist Technol, 2009. **4**(5): p. 373-5.
9. Traballesi, M., et al., *Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study.* Eur J Phys Rehabil Med, 2012.
10. Lehmann, J.F., et al., *Comprehensive analysis of dynamic elastic response feet: Seattle Ankle/Lite Foot versus SACH foot.* Arch Phys Med Rehabil, 1993. **74**(8): p. 853-61.
11. Sam, M., A.H. Hansen, and D.S. Childress, *Mechanical characterization of prosthetic feet using a prosthetic foot loading apparatus.* Proceedings of the 22nd Annual International Conference of the Ieee Engineering in Medicine and Biology Society, Vols 1-4, 2000. **22**: p. 1968-1971.
12. Berge, J.S., G.K. Klute, and J.M. Czerniecki, *Mechanical properties of shock-absorbing pylons used in transtibial prostheses.* J Biomech Eng, 2004. **126**(1): p. 120-2.
13. Gard, S.A. and R.J. Konz, *The effect of a shock-absorbing pylon on the gait of persons with unilateral transtibial amputation.* J Rehabil Res Dev, 2003. **40**(2): p. 109-124.
14. Theeven, P.J.R., et al., *Influence of Advanced Prosthetic Knee Joints on Perceived Performance and Everyday Life Activity Level of Low-Functional Persons with a Transfemoral Amputation or Knee Disarticulation.* Journal of Rehabilitation Medicine, 2012. **44**(5): p. 454-461.
15. Bellmann, M., et al., *Immediate Effects of a New Microprocessor-Controlled Prosthetic Knee Joint: A Comparative Biomechanicall Evaluation.* Arch Phys Med Rehabil, 2012. **93**(3): p. 541-549.
16. Gholizadeh, H., et al., *Transtibial prosthetic socket pistoning: Static evaluation of Seal-In (R) X5 and Dermo (R) Liner using motion analysis system.* Clinical Biomechanics, 2012. **27**(1): p. 34-39.

17. Sanders, J.E., et al., *Testing of elastomeric liners used in limb prosthetics: Classification of 15 products by mechanical performance.* J Rehabil Res Dev, 2004. **41**(2): p. 175-185.
18. Sanders, J.E., et al., *Material properties of commonly-used interface materials and their static coefficients of friction with skin and socks.* J Rehabil Res Dev, 1998. **35**(2): p. 161-76.

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James Schweitzer for acquisition of mechanical pump data.

Kerice Tucker for mechanical pump testing setup and training.

Figure Captions

Figure 1 Schematic of experimental test setup for electrical and mechanical pumps showing fixed volume chambers, digital pressure gauge and servo-hydraulic materials testing system. The volumes of the five PVC chambers used for testing from left to right are (A) 2.05E-4 m^3[12.54 in^3], (B) 1.40E-4 m^3[8.52 in^3], (C) 1.06E-4 m^3[6.46 in^3], (D) 7.52E-5 m^3[4.59 in^3] and (E) 4.41E-5 m^3[2.69 in^3]. Inserts show the fixture attachment within the materials testing machine for (a) Harmony® P2, (b) Harmony® HD and (c) Harmony® P3. The bottom right insert is the displacement loading profile for the mechanical pump tests.

Figure 2 Electrical pump battery depletion test results. (a) Plot of vacuum pressure versus time for two grouped evacuation trials of the Harmony® e-Pulse and the single group evacuation trial of the LimbLogic® VS. (b) Boxplot indicating substantially lower median activation time for LimbLogic® VS compared to both groups of data from the Harmony® e-Pulse.

Figure 3 Electrical pump results showing average evacuation time versus exact chamber volumes. Evacuation times of the Harmony® e-Pulse (superior line, T_{eP}) are consistently higher than evacuation times of the LimbLogic® VS (inferior line, T_{LL}).

Figure 4 Mechanical pump results showing (Top plots) time to evacuate chambers to 5.76E4 Pa [17 inHg] for pump settings (x-axis) and (Bottom plots) maximum force exerted by the testing system for each chamber evacuated: (a) Harmony® P2, (b) Harmony® HD and (c) Harmony® P3.

Table 1 Description of vacuum pumps tested.

Electrical Pumps	
Harmony® e-Pulse (Otto Bock)	• 2.20 Wh nominal battery energy • 600 mbar[18 inHg] maximum negative pressure level
LimbLogic® VS (WillowWood)	• 2.04 Wh nominal battery energy • 677 mbar[20 inHg] maximum negative pressure level
Mechanical Pumps	
Harmony® P2 (Otto Bock)	• Patient weights of 50 – 100 kg [110 – 220 lbs] • Vacuum capability of 508-847 mbar [15-25 inHg]
Harmony® HD (Otto Bock)	• Patient weights of 100 – 150 kg [220-330 lbs] • Vacuum capability of 508-847 mbar [15 – 25 inHg]
Harmony® P3 (Otto Bock)	• Patient weights of 45 – 100 kg [100 – 220 lbs] • Functional rings denoted 0-4 in order of increasing resistance to compression • Vacuum capability of 508-847 mbar [15 – 25 inHg]

Table 2 Weight settings for mechanical pumps.

Setting	Number of turns out (counterclockwise) from fully inserted position**	Harmony® P2	Harmony® HD	Harmony® P3		
		Corresponding Patient Weight (lbs/kg)		Functional Ring	Body Weight (kg)	Load (lbs)
***Setting 1**	**4.5**	**120 / 50**	**220 / 100**	0	45-50	100-110
Setting 2	4.0	140 / 60	240 / 110	1	50-60	110-130
Setting 3	3.5	160 / 70	260 / 120	2	60-73	130-160
***Setting 4**	**3.0**	**180 / 80**	**280 / 130**	3	73-86	160-190
Setting 5	2.5	200 / 90	300 / 140	4	86-100	190-200
***Setting 6**	**2.0**	**220 / 100**	**320 / 150**			

*Settings used for bench-top testing.

**Manufacturer instructions: To adjust settings, locate blue cup inside pump shaft, screw in completely using 3/8" Allen wrench. Set elastomer rod by backing out the blue cup completely to release pressure on the rod, then turning clockwise by suggested number of turns.

Table 3 Electrical pump results.

Chamber Volume (m^3/in^3)	Evacuation Pressure (Pa/inHg)	Time to Evacuate (seconds)	
		LimbLogic® VS	Harmony® e-Pulse
2.05E-4/12.54	5.76E4/17	20.16	31.56
1.40E-4/8.52	5.76E4/17	13.38	21.32
1.06E-4/6.46	5.76E4/17	11.28	17.37
7.52E-5/4.59	5.76E4/17	7.95	12.06
4.41E-5/2.69	5.76E4/17	5.10	7.86
	Average	11.57	18.04
	Standard Deviation	5.74	9.13

Table 4 Mechanical pump results.

	Harmony® P2			Harmony® HD			Harmony® P3			
	Settings			Settings			Functional Rings			
	1	4	6	1	4	6	0	1	2	3	4
Time to evacuate to 5.76E4 Pa [17 inHg] (seconds)	42.72	42.59	42.71	42.47	43.31	43.06	39.50	41.78	53.31	62.12	79.17
Number of cycles to 5.76E4 Pa [17 inHg] (units)	26	25	25	26	25	25	25	27	34	39	50
Max. vacuum (MPa/ inHg)	80.39/ 23.74	89.43/ 26.41	89.43/ 26.41	88.93/ 26.26	88.38/ 26.10	88.69/ 26.19	75.11/ 22.18	70.40/ 20.79	67.90/ 20.05	65.15/ 19.24	63.16/ 18.65

Figure 1

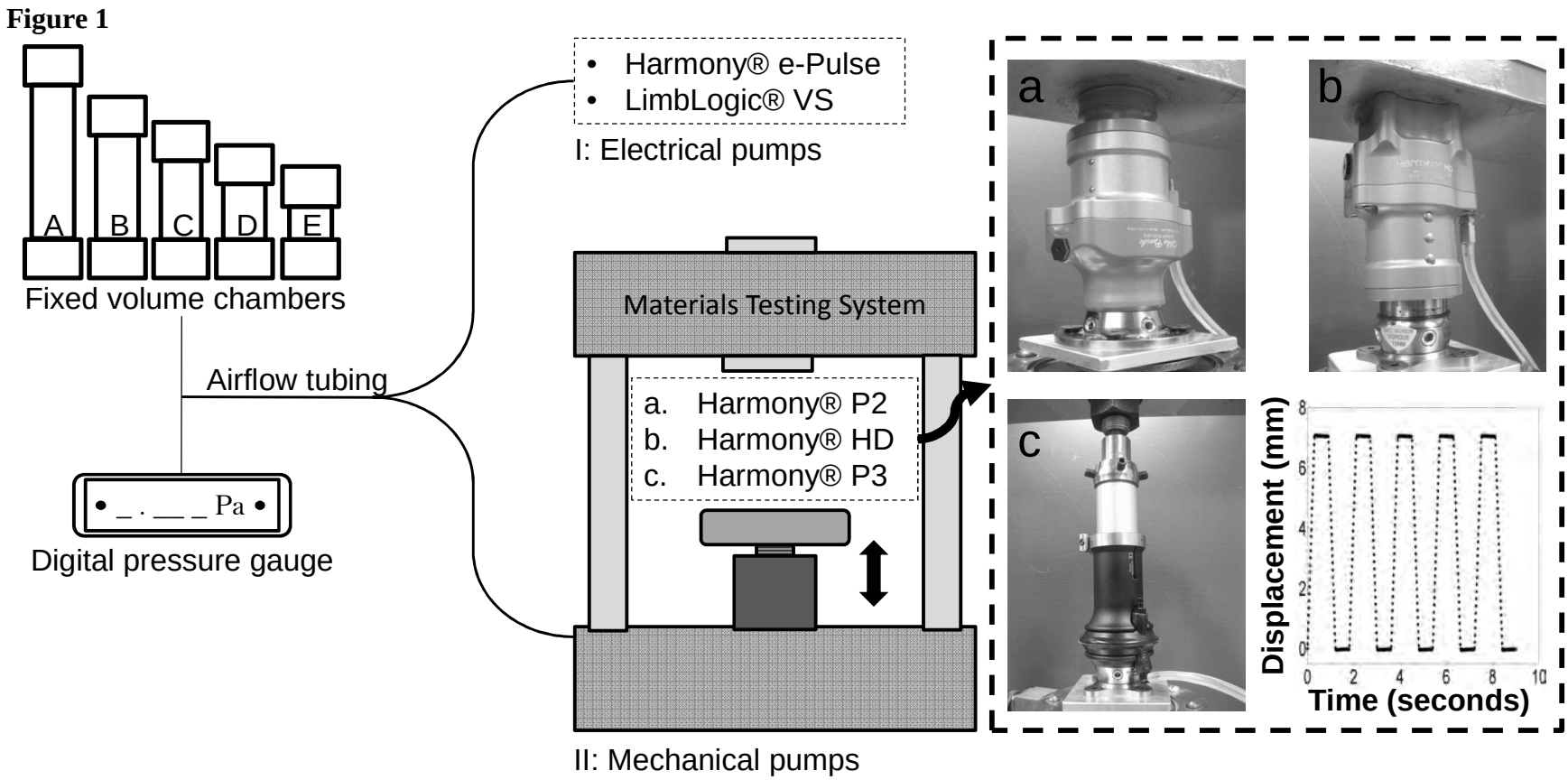

A
B
C
D
E
Fixed volume chambers
Airflow tubing
Pa
Digital pressure gauge
• Harmony® e-Pulse
• LimbLogic® VS
I: Electrical pumps
Materials Testing System
a. Harmony® P2
b. Harmony® HD
c. Harmony® P3
II: Mechanical pumps
a
b
c
Displacement (mm)
Time (seconds)

Figure 2

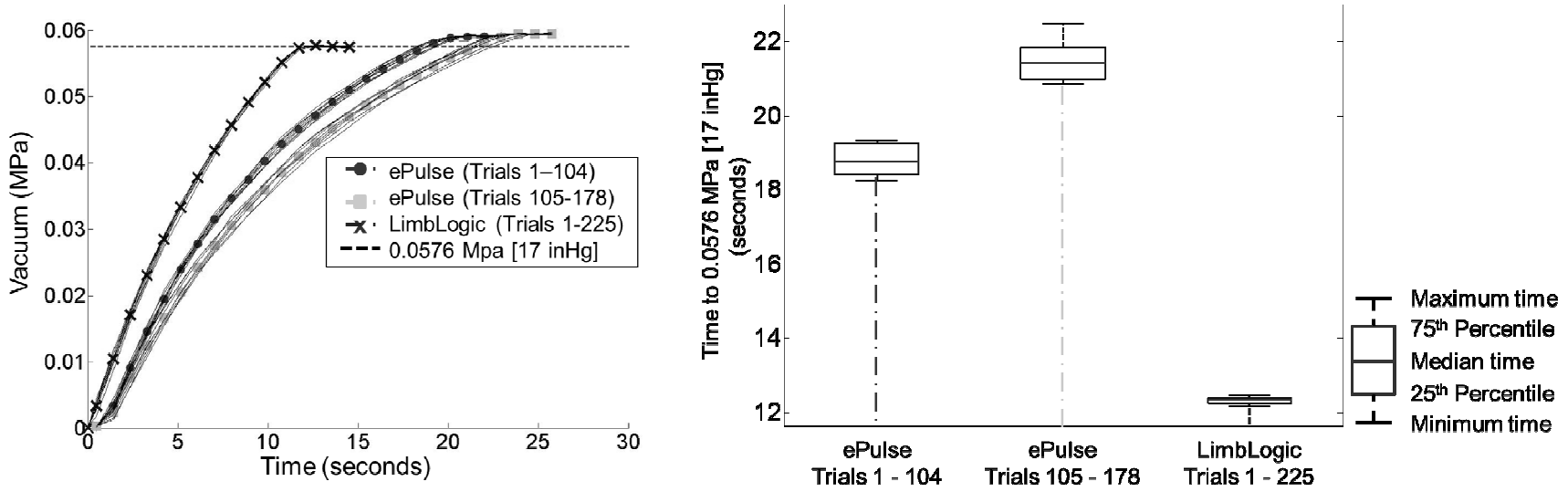

Vacuum (MPa)
Time (seconds)
ePulse (Trials 1–104)
ePulse (Trials 105-178)
LimbLogic (Trials 1-225)
0.0576 Mpa [17 inHg]
Time to 0.0576 MPa [17 inHg] (seconds)
ePulse Trials 1 - 104
ePulse Trials 105 - 178
LimbLogic Trials 1 - 225
Maximum time
75th Percentile
Median time
25th Percentile
Minimum time

Figure 3

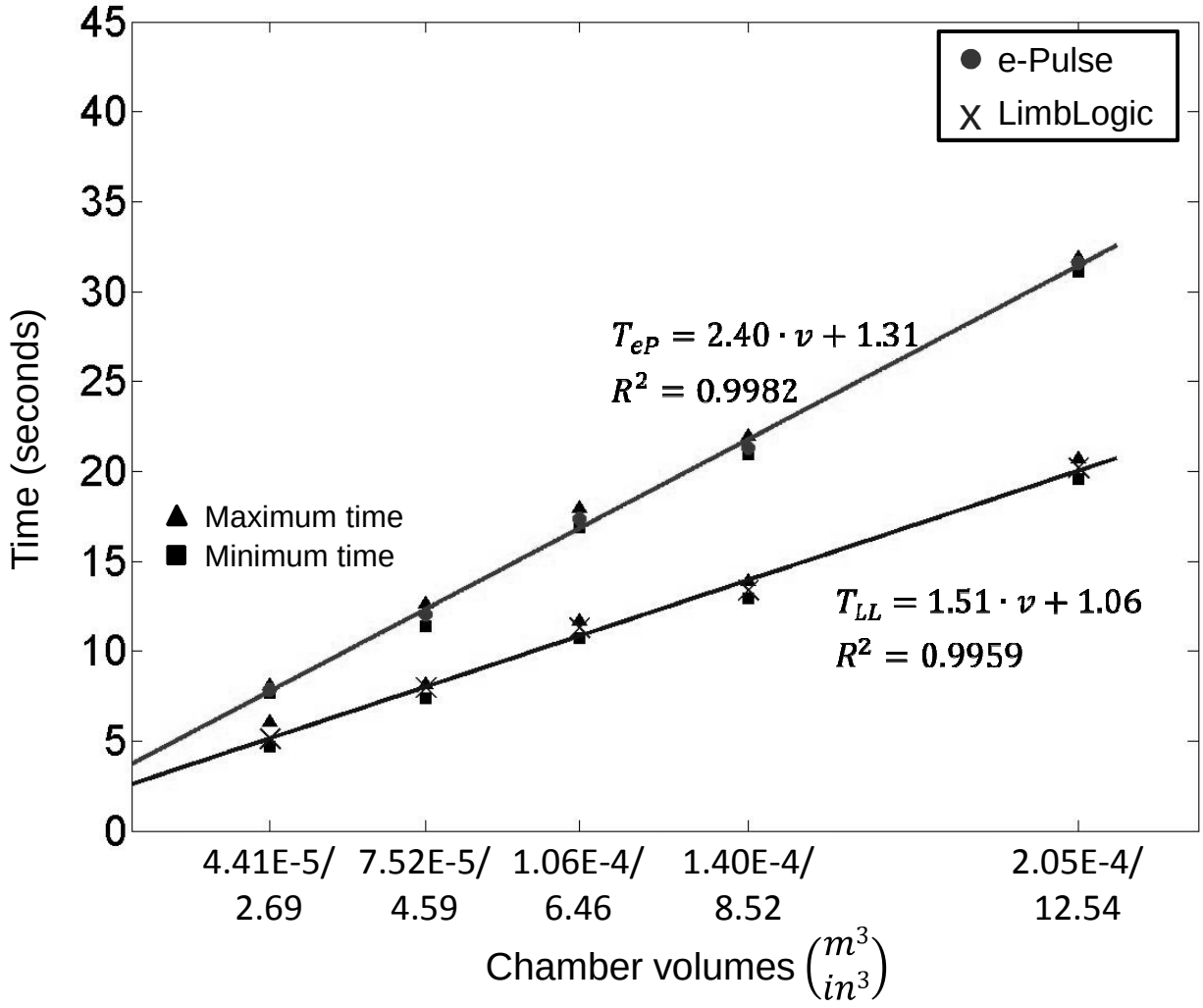
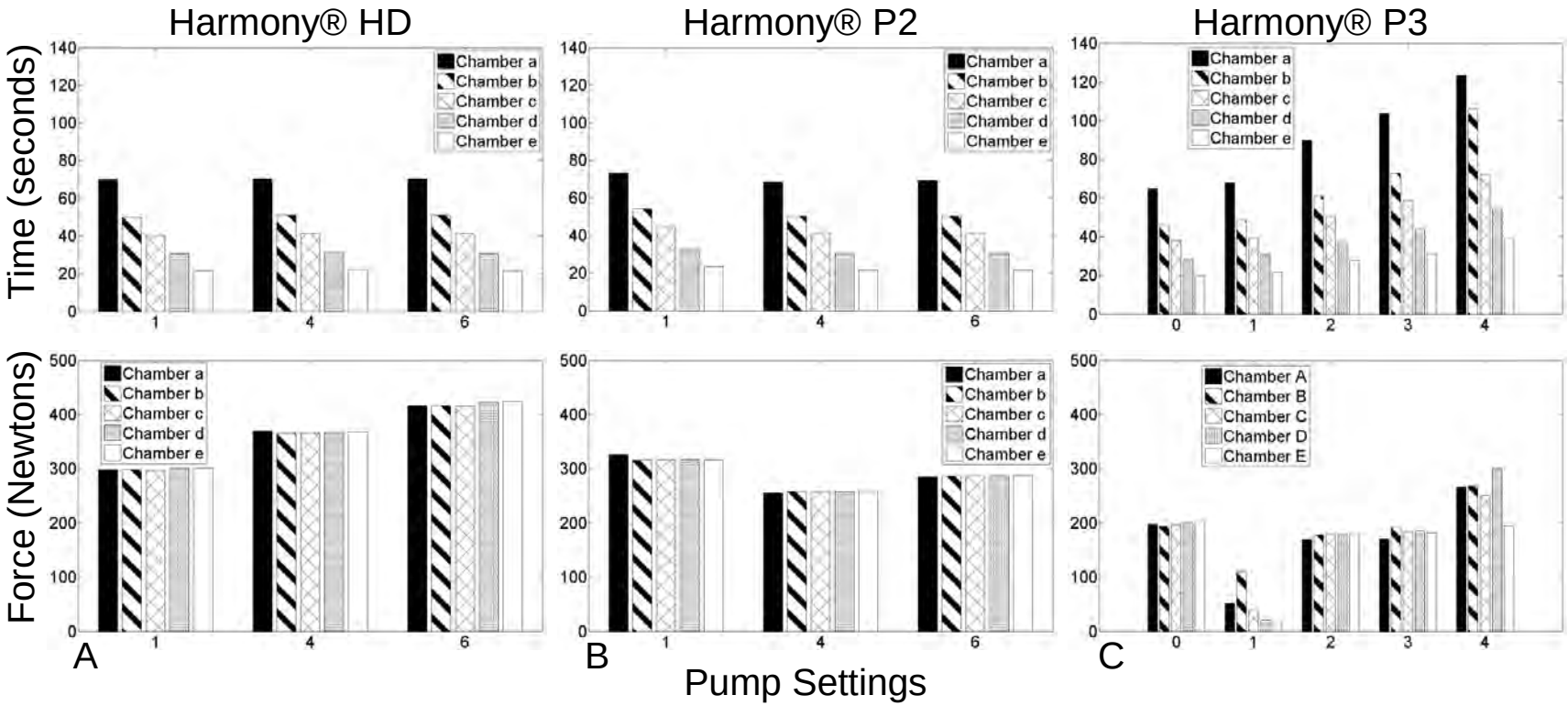

e-Pulse
LimbLogic
$T_{eP} = 2.40 \cdot v + 1.31$
$R^2 = 0.9982$
$T_{LL} = 1.51 \cdot v + 1.06$
$R^2 = 0.9959$
Maximum time
Minimum time
Time (seconds)
0
5
10
15
20
25
30
35
40
45
4.41E-5/ 2.69
7.52E-5/ 4.59
1.06E-4/ 6.46
1.40E-4/ 8.52
2.05E-4/ 12.54
Chamber volumes $\left(\frac{m^3}{in^3}\right)$

Figure 4


Harmony® HD
Harmony® P2
Harmony® P3
Time (seconds)
Force (Newtons)
Chamber a
Chamber b
Chamber c
Chamber d
Chamber e
Chamber A
Chamber B
Chamber C
Chamber D
Chamber E
A
B
C
Pump Settings

APPENDIX F

Coauthors

Caldwell RJ, Komolafe OA, Fatone, S

Title: 150 characters

Clinical outcomes using a new subischial socket with vacuum assisted suspension: the NU-FlexSIV

Summary: 300 characters

The interface between socket and residual limb is crucial to the overall success of the prosthesis user. Improved technology in liners and active vacuum systems allows prosthetists to lower transfemoral socket trim lines without compromising clinical outcomes.

Introduction: 1000 characters

There are two basic designs of prosthetic sockets for persons with a transfemoral amputation in use today both of which intentionally interact with the pelvis. Lowering the proximal trim line of a transfemoral socket is appealing because the proximal brim contributes to discomfort during sitting and limits hip range of motion. However, lower trim lines challenge conventional understanding of the biomechanics of transfemoral sockets, especially regarding coronal plane stability. A subischial socket has been proposed with proximal trim lines located distal to the ischial tuberosity and not intended to interact with the pelvis. Working in concert with vacuum assisted suspension, the Northwestern University Flexible SubIschial Vacuum (NU-FlexSIV) socket was designed to allow greater range of motion, increased comfort, and uncompromised control for the transfemoral prosthesis user. Socket design is described and case studies are presented to illustrate clinical outcomes.

Methods: 1000 characters

The NU-FlexSIV socket system was developed iteratively over many clinical fittings and then reverse engineered to improve understanding of function. The current design consists of an undersized flexible single-wall socket with an embedded frame, an undersized silicone liner reflected over the proximal socket edge and a sealing sleeve. The undersized socket and liner compress the limb, stiffening the soft tissue. This stiffening is thought to decrease relative motion of the residual limb within the socket. The embedded frame allows force transmission between the residual limb and prosthesis while maximizing overall socket flexibility. The impression is taken over the silicone liner with the patient seated with the limb flexed and abducted to allow gravity to pre-modify the tissues. Rectifications specific to this socket design are made to the positive model to ensure comfort and coupling in sitting and standing.

Results: 1500 characters

Approximately 100 clinical fittings have been conducted with this socket technology. Examples of clinical case studies will be presented demonstrating application of the NU-FlexSIV socket system. Cases with varying limb tissue types; limb lengths and skin conditions will be presented. Videos of subjects will be used to demonstrate symmetrical and uncompromised gait comparing subischial and ischial containment sockets. Improvements in limb health and tissue quality after use of the NU-FlexSIV socket system will be highlighted.

Conclusion: 1000 characters

We have developed a new socket for use by persons with transfemoral amputation that appears to provide improved comfort without loss of function. Clinically we have observed no detriments to gait compared to conventional sockets, tissue issues have improved, and an increase in subjects overall activity levels.